APPENDIX J

SURVEY PROCEDURES AND INTERPRETIVE GUIDELINES FOR INTERMEDIATE CARE FACILITIES FOR PERSONS WITH MENTAL RETARDATION

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SURVEY PROCEDURES FOR INTERMEDIATE CARE FACILITIES FOR PERSONS WITH MENTAL RETARDATION (ICFs/MR)

PART 1

INTERPRETIVE GUIDELINES FOR INTERMEDIATE CARE FACILITIES FOR PERSONS WITH MENTAL RETARDATION

PART 2

I. INTRODUCTION

This revised ICF/MR survey protocol is to assist surveyors to focus attention on the outcomes of individualized active treatment services. The Health Care Financing Administration (HCFA) intends the revised survey process to be less resource intensive for providers who consistently demonstrate compliance with the regulations. The survey process is based on the October 3, 1988 regulation and is applicable to all ICFs/MR, regardless of size.

In 1988, when the current ICF/MR regulation was implemented, it was viewed as a great step forward in promoting a focus on the actual outcomes experienced by consumers, rather than on the policies, procedures and paperwork of the facility. Since that time there has been an evolution on thinking in both the field of developmental disabilities (DD) and in the field of quality assurance (QA).

The field of DD is increasingly emphasizing supporting individuals in their own homes and communities, rather than placing people in facilities. In addition services in virtually all States are placing increased emphasis on person-centered planning and person-centered services that focus on the preferences, goals and aspirations of each individual and on supporting them in reaching their personal goals. The field of QA is placing increased emphasis on outcomes related to choice, control, relationships, community inclusion, and satisfaction with life, as well as satisfaction with services and supports. Many QA systems also include organizational self-assessment and continuous quality improvement components. These trends have contributed to the perception by providers and advocates that the ICF/MR regulation and oversight process is too prescriptive and cumbersome, and should be altered to reflect newer values of quality enhancement and continuous quality improvement.

This revised survey protocol gives facilities broader latitude to develop the processes by which it implements active treatment services. While the facility practice must comply with the requirements of 42 CFR 483, Subpart I, the survey is to center on the fundamental requirements that produce outcomes for individuals. When those outcomes occur, review of additional supporting requirements of process and structure is not indicated.

A survey which focuses on observations of staff/consumer interaction and on interviews with consumers regarding their participation and choice of services is sufficiently informative to determine the outcomes of active treatment. In the presence of problems, a more in-depth review of how the process unfolded for a particular individual(s) occurs.

A facility may receive reimbursement only for the cost of care of individuals classified as eligible for the ICF/MR level of care who are receiving active treatment. Determine facility compliance with Conditions of Participation and with standards in the context of individual experiences within the facility. When performing certification surveys to assess facility compliance, assess whether individuals are receiving needed active treatment services.

II. PRINCIPAL FOCUS OF SURVEYS

The principal focus of the survey is on the "outcome" of the facility's implementation of ICF/MR active treatment services. Direct your principal attention to what actually happens to individuals: whether the facility provides needed services and interventions; whether the facility insures

individuals are free from abuse, mistreatment, or neglect; whether individuals, families and guardians participate in identifying and selecting services; whether the facility promotes greater independence, choice, integration and productivity; how competently and effectively the staff interact with individuals; and whether all health needs are being met.

Use observation and interview as the primary methods of information gathering. Conduct record reviews after completion of observations and interviews to confirm specific issues. Verify that the facility develops interventions and supports that address the individuals' needs, and provides required individual protections and health services. Do not conduct in-depth reviews of assessments, progress notes or historical data unless outcomes fail to occur for individuals.

III. SURVEY PROCESS

The survey process is divided into three stages. They are the fundamental, extended and full survey. **(Note: These stages do not apply to the Life Safety Code survey. Every certification and annual re-certification requires a complete Life Safety Code survey (see instructions in Appendix I)).**

A. Fundamental Survey.--A fundamental survey is conducted to determine the quality of services and supports received by individuals, as measured by outcomes for individuals and essential components of a system which must be present for the outcomes of active treatment to occur. Certain requirements are designated as fundamental and are reviewed first. The remaining requirements (that are not designated as fundamental) are supporting structures or processes that the facility must implement. A decision that a provider is in compliance with the fundamental requirements indicates an outcome-reviewed compliance with the non-fundamental requirements and associated conditions of participation. Focus initial attention on the fundamental requirements of the conditions of participation for:

42 CFR 483.420 Client Protections

Fundamental requirements:

483.420(a)(2) - (7)	W124 - W130
483.420(a)(9)	W133
483.420(a)(11) - (12)	W136 - W137
483.420(c)(1) - (6)	W143 - W148
483.420(d)(2) - (4)	W153 - W157

42 CFR 483.440 Active Treatment Services

Fundamental requirements:

483.440(a)(1) - (2)	W196 - W197
483.440(c)(2)	W209
483.440(c)(4)	W227
483.440(c)(6)(i)	W240
483.440(c)(6)(111)	W242
483.440(c)(6)(vi)	W247
483.440(d)(1)	W249
483.440(f)(1)	W255 - W257
483.440(f)(3)(i) - (ii)	W262 - W263

In addition include:

483.410(d)(3)	W120
483.430(d)(2)	W186
483.470(g)(2)	W436
483.470(i)(4)	W448 - W449

42 CFR 483.450 Client Behavior and Facility Practices

Fundamental requirements:

483.450(b)(2)	W285
483.450(b)(3)	W286 - W288
483.450(c)(1)	W291
483.450(c)(3)	W293
483.450(d)(4)	W301 - W302
483.450(e)(3)	W313
483.450(e)(4)(i)	W314

42 CFR 483.460 Health Care Services

Fundamental requirements:

483.460(a)(3)	W322
483.460(c)	W331
483.460(c)(3)(v)	W338
483.460(g)(2)	W356
483.460(k)(2)	W369
483.460(k)(4)	W371

All fundamental requirements must be reviewed in every annual recertification survey. When observations and interviews are complete, review the individuals' records, as needed, to verify observation and interview findings. If indicated, verify that individual health needs are met and protections are in place. When the fundamental requirements are "met", the facility meets the Conditions of Participation.

When fundamental requirements are "not met", review the condition-level compliance principles found in the interpretive guidelines for W122, W195, W266, and W318. Determine whether deficiencies at the fundamental requirements, when viewed as a whole, lead you to believe that one or more of the "not met" compliance principles is present. If this is the case, conduct an extended survey, as instructed below. When the "met" compliance principles are present, the facility is assumed to be in compliance with all conditions of participation. This is the end of the fundamental survey. The survey agency would prepare a Form HCFA-2567, Statement of Deficiencies, and report any standard-level deficiencies based on the findings from the fundamental survey.

B. Extended Survey.--An extended survey is conducted when standard-level deficiencies are found during the fundamental survey and the survey team has determined or suspects that one or more Conditions of Participation examined during the fundamental survey (42 CFR 483.420, 42 CFR 483.440, 42 CFR 483.450, and 42 CFR 483.460) are "not met." The team would need to gather additional information in order to identify the structural and process requirements that are "not met" and to support their condition-level compliance decision. The team reviews all of the requirements within the Condition(s) for which compliance is in doubt. Using the condition-level compliance principles in the interpretive guidelines as a guide, determine if the facility complies with the relevant Condition(s) of Participation.

When the survey team determines that the facility is in compliance with the relevant Conditions of Participation, conclude the survey and prepare a HCFA-2567 for facility practices not in compliance with standards. When the facility is not in compliance with one or more Conditions of Participation, prepare a HCFA-2567 describing the deficient facility practices which are not in compliance with the Conditions of Participation of either 42 CFR 483.420, 42 CFR 483.440, 42 CFR 483.450, or 42 CFR 483.460. Base any required adverse action on these findings. Review of additional requirements under other

Conditions of Participation is at the option of the survey agency based on the criteria under paragraph "C" of this section.

NOTE: Neither the fundamental or the extended survey process preclude the survey agency from review of any standard, if evidence of non-compliant facility practice is suspected during any survey.

C. Full Survey.--A full survey is conducted at an initial survey and at the discretion of the survey agency, based on the survey agency's identification of concerns related to the provider's capacity to furnish adequate services. This decision may be based on criteria, including but not limited to, the following:

- o A condition-level deficiency on the previous year's recertification survey,
- o The existence of a time-limited agreement of less than twelve months due to programmatic deficiencies, or

- o Evidence related to diminished capacity to provide services based on other sources, such as complaints, inspection of care findings or State licensure deficiencies that are relevant to Federal requirements.

The team reviews all the requirements in all Conditions of Participation to determine if the facility maintains the process and structure necessary to achieve the required outcomes. Based on the information collected, determine whether facility practice is in compliance with all Conditions of Participation.

IV. COMPONENTS OF ACTIVE TREATMENT

The definition of "active treatment in intermediate care facilities for persons with mental retardation" in 42 CFR 435.1009 refers to treatment that meets the requirements specified in the standard for active treatment 42 CFR 483.440(a). The components of the active treatment process are:

A. Comprehensive Functional Assessment (42 CFR 483.440(c)(3)).--The individual's interdisciplinary team must produce accurate, comprehensive functional assessment data, within 30 days after admission, that identify all of the individual's:

- o Specific developmental strengths, including individual preferences;
- o Specific functional and adaptive social skills the individual needs to acquire;
- o Presenting disabilities, and when possible their causes; and
- o Need for services without regard to their availability.

B. Individual Program Plan (IPP) (42 CFR 483.440(c)).--The interdisciplinary team must prepare an IPP which includes opportunities for individual choice and self-management and identifies: the discrete, measurable, criteria-based objectives the individual is to achieve; and the specific individualized program of specialized and generic strategies, supports, and techniques to be employed. The IPP must be directed toward the acquisition of the behaviors necessary for the individual to function with as much self-determination and independence as possible, and the prevention or deceleration of regression or loss of current optimal functional status.

C. Program Implementation (42 CFR 483.440(d)).--Each individual must receive a continuous active treatment program consisting of needed interventions and services in sufficient intensity and frequency to support the achievement of IPP objectives.

D. Program Documentation (42 CFR 483.440(e)).--Accurate, systematic, behaviorally stated data about the individual's performance toward meeting the criteria stated in IPP objectives serves as the basis for necessary change and revision to the program.

E. Program Monitoring and Change (42 CFR 483.440(f)).--At least annually, the comprehensive functional assessment of each individual is reviewed by the interdisciplinary team for its relevancy and updated, as needed. The IPP is revised, as appropriate.

V. TASK 1 - SAMPLE SELECTION

A. Purpose of the Sample.--The purpose of drawing a sample of individuals from the facility is to reflect a proportionate representation of individuals by the four functional levels (mild, moderate, severe, and profound mental retardation) as defined by the American Association on Mental Deficiency, Classification in Mental Retardation (eighth edition, 1983).

The sampling process is not designed to produce a "statistically valid" sample. Apply the method with flexibility based upon the prevailing developmental strengths and needs presented by the individuals served by the facility. A "statistically valid" sample would not accommodate this need.

While the individuals in the sample are targeted for observation and interview, conduct each program audit of the individual within the context of each of the environments in which the individual lives, works, and spends major leisure time. Although you focus on the individual, the behavior and interactions of all other individuals and staff within those environments also contribute to the total context and conditions for active treatment. Therefore, other individuals will be included in the overall sample.

As the sample is built, additional information about the facility's services and special individual needs may emerge. If you find that a disproportionate number of disabilities or needs are present within the facility's population add to or replace originally selected individuals of the same functional level in the program audit sample to ensure that the appropriate care and services are reviewed. Staff interview for individual characteristics (see the back of Form HCFA-3070G) may help identify areas of individual need that should be reflected in the sample.

For example, if you discover a significant percentage of individuals are nonambulatory, and this characteristic has not been represented in the sample, add additional individuals. Likewise, if while observing Individual A (a member of the sample), you note that Individual B (who was not targeted for the sample) engages in a particular problematic behavior for which staff do not appear to provide appropriate intervention, add Individual B to the sample in order to probe further if needs are addressed. You are free by this methodology to add to the sample on an as needed basis.

B. Sample Size.--Calculate the size of the sample by the following guidance:

Number of Individuals residing in the Facility	Number of Individuals in the Sample	Number of Interviews with Individual/Family
4 - 8	50 percent	50 percent of sample
9 - 16	4	4
17 - 50	8	5
51 - 100	10	5
101 - 500	10 percent	50 percent of sample (max.: 15)
Over 500	50	15

C. Sample Selection.--Do not allow the facility staff to select the sample.

1. Facilities Serving 100 or Fewer Individuals.--Draw a sample that evenly distributes the individuals among buildings and functioning levels. Usually, this can be done by asking the staff to provide a full list of the individuals with their building locatons and functional levels and you choosing the names.

2. Facilities with over 100 individuals.--

o Request a listing of all individuals by overall functional (cognitive and adaptive) level (i.e., mild, moderate, severe, profound) and building location.

o Determine the number of individuals to draw based upon the total individuals from Section III B.

o Determine the percentage occurrence of each functional level in the overall population (e.g., 12 percent mild; 24 percent moderate; 63 percent severe).

o Determine the number of individuals to draw in each functional category (for example, if the sample size is 50, and 12 percent of the individuals have mild mental retardation, then multiply 50 by .12 = 6, and draw 6 individuals who have mild mental retardation into the sample).

o Draw the sample for each functional category. (Assume there are 60 with mild mental retardation, and 6 are to be sampled. Divide 60 by 6 = 10, and draw every tenth individual.) The interval of selection varies with each functional category because there will be a different percentage occurrence at each. Thus, assuming there are 16 individuals with severe mental retardation and 4 are to be sampled, draw every fourth name from the list of individuals with severe mental retardation.

o Locate each selected individual's living unit on a map of the facility building(s) to see if too many are concentrated in too few buildings. To provide a comprehensive look at the facility, drop some individuals and add others in other buildings for a better distribution. Each individual replacing an originally selected individual must be of the same functional level.

3. Alternate Sampling Procedure.--In the rare situation in which the facility is unable to produce the necessary data on which to draw the sample, draw a random sample, to the maximum extent possible. Supplement it as described in Section VA.

Mental retardation, as defined by the American Association on Mental Retardation (AAMR) in Mental Retardation: Definition, Classification and Systems of Supports (ninth edition, 1992), is no longer classified in four functional levels (mild, moderate, severe, and profound.) Most facilities have not yet adopted the 1992 classification system; however, when the facility does use the 1992 classification system and information regarding the four functional levels is not available, revise the sampling procedure. Follow the instructions in A and B above but, instead of using the four functional levels referenced in AAMR's Classification System of 1983, use the four levels of intensity of supports (intermittent, limited, extensive, and pervasive) on Dimension I for Self-Care from the new classification system. Although not equivalent to the 1993 classifications, this method should provide a sample of individuals within the facility who represent a variety of functional abilities.

D. Program Audit Approach.--To maximize the advantage of an interdisciplinary survey team, the team leader assigns each member an equitable number of individuals on whom to focus. For each individual, assess all applicable fundamental requirements of the ICF/MR Conditions of Participation based on the individual's need for that particular service. Each member of the team shares salient data about findings relative to his or her assigned individuals. Consult with one another, on a regular basis during the survey, to maximize sharing of knowledge and competencies.

E. Sampling on Follow-up Survey.--The purpose of the follow-up survey is to verify correction of deficiencies previously cited on the HCFA-2567. It is NOT necessary to do a full review of all services being received, only those areas in which deficiencies were previously cited. Sample selection on the follow-up survey is, therefore, dependent on the nature of the deficiencies for which follow-up must be done.

If the last survey found multiple standard-level deficiencies that are not limited to a specific area or issue, follow the procedure described in paragraphs A through D above to select a new sample and use the same sample size specified in paragraph B. This procedure may result in inclusion of some individuals from the previous sample, however, approximately 50% of the sample on the follow-up survey should be individuals who were not previously reviewed in order to assure systemic correction of the identified deficiencies. This can be accomplished by beginning the interval of selection at a different point on the list of individuals residing at the facility. The maximum sample size on a follow-up survey is 30.

When Conditions of Participation have been found not met in the annual survey and the types of deficiencies are limited to a specific need or service area, then the follow-up sample may be drawn from the specific universe of individuals who have that specific need. To select the sample, start with the total number of individuals affected by the specific need, then choose the sample size. The sample universe will be the total number of individuals who have that specific need. For example, if the facility has 20 individuals receiving medications to manage behavior, the sample size would be 8, in accordance with paragraph B.

VI. TASK 2 -REVIEW OF FACILITY SYSTEMS TO PREVENT ABUSE, NEGLECT AND MISTREATMENT AND TO RESOLVE COMPLAINTS

During the entrance conference, determine how the facility resolves individual complaints and allegations of abuse, mistreatment and neglect. While no specific system is required, 42 CFR 483.420(d)(4) does require that the results of all investigations are reported to the administrator and are reported in

accordance with State law. The facility, therefore, should have a reproducible mechanism to assure its responsiveness to concerns of individuals and their families. That system must assure prompt detection, reporting, investigation and resolution of complaints and of allegations and occurrences of abuse, mistreatment and neglect and injuries from unknown sources.

Review the facility's system (e.g., accident and injury logs and reports) for any evidence that suggests that individuals are being abused or are vulnerable to abuse and injury. Data that is derived from these reports are important in the event that you find an immediate and serious threat to an individual's health and safety. If you discern any patterns that suggest abuse, follow up on the status and condition of those individuals. Also review investigations completed and those in process to determine that the facility protects individuals from abuse, mistreatment and neglect while the allegation is under investigation. If the State law or regulation requires the facility to report such allegation to other agencies, determine that this occurs.

Conducting this review early in the survey process facilitates any necessary follow-up during later observations, interviews or record reviews of individuals. Use the Interpretive Guidelines and Additional Data Probes at 42 CFR 483.420(a)(5) or W127 for further guidance. If you believe serious and immediate threat to individual's health and safety exists, consult Appendix Q.

VII. TASK 3 - INDIVIDUAL OBSERVATIONS

Upon completion of Task 2, surveyors are to conduct observations of the individuals selected for the sample. DO NOT:

- Conduct a detailed review of individual's records;
- Conduct an inspection tour of the facility's environment; or
- Request facility staff to keep people home from scheduled activities, such as work or day programs.

A. Purpose.--Determine if the necessary relationship between the individual's needs and preferences, and what staff know and do with individuals, in both formal and informal settings throughout the day and evening, is made.

As a result of any observation, the surveyor should be able to determine whether:

- Competent interaction occurs between staff and the individual(s);
- Individuals are given the opportunity to exercise choice and function with as much self-determination and independence as possible; and
- Staff provide the needed supports and interventions to increase skills or prevent loss of functioning.

The primary purpose of the visit to the out-of-home program is to determine whether the individual is receiving services that promote growth and independence and how the residence assures consistent delivery of services. Generally the out-of-home program and residence should be using the same interventions, communication methods, and behavior shaping strategies. If not, determine the justification for the difference in services. For example, if the day program is using physical restraints as an intervention and the home is not, determine the justification for the restraints.

B. Survey Conduct.--Be present when individuals are present. If individuals are in a program other than in the residence, go to that location. Observe each person in the sample in the home environment and in the day

program. Observations across the entire survey (e.g., early morning, afternoon and evening observations) are absolutely essential. One method to conduct observations over this time span is to alter the work day of the survey team members. For example, some members might work from 6:30 a.m. to 3:00 p.m., while others work from 1:00 p.m. to 9:30 p.m.

Schedule your time to observe special training programs that are critical to the individuals' development. Use your observations to determine if individual training is carried out consistently at all appropriate times throughout the day. Observations of meal times, individuals' communication with staff and others, behavior shaping interventions, and routine activities should reflect a consistent pattern of interaction with the individual and demonstrate the staff's knowledge of the individual. Take steps to validate any discrepancies noted. Additional observations within similar situations, locations or activities may be necessary to identify a systemic deficient practice as opposed to a one time occurrence.

Show respect for the individuals' home and their privacy. As a courtesy, alway request permission before entering a bedroom. Do not observe activities in which individuals are undressed unless that observation is essential to your assessment of facility compliance and the information cannot be obtained from other reliable sources. Most information about routine hygiene activities during which individuals are undressed can be obtained through interview of individuals or staff. As a general policy, it is preferable to ask permission to make these types of observations from the individual, or from the staff person who is present if the individual cannot communicate. An individual's request not to be observed while undressed should be honored, when possible. The surveyor does have authority, however, to access information that is essential to determining compliance without asking permission. This authority may need to be exercised in regard to an individual who is undressed, for example, in order to observe for bruises or other signs of injury when it is suspected that the individual is being abused. These observations should be conducted in private, with as little of the body exposed as possible, and with a staff person present. Consent from staff or guardians is not required in order to access information or make observations.

For individuals who are working in competitive employment sites, ask the individual's permission to visit that site. If the individual is unable to communicate, discuss with the staff the advisability of visiting the competitive site. The intent is that the individual is not identified as different from other workers at the site. If the individual works in a restaurant, for example, you may be able to visit as a "customer" to observe the work environment. If an interview with a job supervisor or support person is indicated, attempt to conduct this interview in a private or inconspicuous area. Upon arrival, introduce yourself to the individual and to the staff and explain the purpose of your visit.

C. Observation Procedure.--Initially the surveyor should note the general impressions of the area. Note things such as:

1. General Impressions.--
   - o How are individuals dressed?
   - o What activities are taking place?
   - o What materials and supplies are present?
   - o Is the environment pleasant and conducive to learning? (e.g., odors, noise, furniture, and adequate bathroom facilities)
   - o How many staff are present? How many individuals?
   - o What types of adaptive equipment or assistive devices are used?

2. Specific Activities and Interactions.--After noting the general setting, the surveyor should begin to focus on the specific activities and interactions. For example:

o Are individuals involved and participating in the activity? Are the activities active or passive? Does the activity appear to have a purpose? Are staff able to explain how the activity is promoting greater independence for each of the individuals present?

o Are there supplies and materials used to assist the individuals? Do individuals use the materials? Do they seem appropriate for the task or activity? Are they appropriate for the individuals?

o What interaction is occurring between staff and individuals? Do the interactions give evidence of respect, dignity? Do staff recognize efforts made by the individuals and provide positive reinforcement?

o Is the number of staff present sufficient for the number of individuals based on the individual needs or the type of activity?

o Are individuals encouraged to make their own choices and decisions? Are they encouraged to complete tasks with as much independence as possible? Are staff doing the activity for the person, or is the person encouraged to do things for him or herself?

o Are any maladaptive behaviors exhibited? How do staff respond?

o Are any individuals ignored or isolated from the activity? If so, what is the reason or justification for this?

3. Individuals in Sample.--The third step of the observation process focuses on the individual(s) in the sample. The surveyor should specifically note:

o What is the appearance of the individual? Is the individual dressed neatly? Does the person appear clean and is his/her hair combed?

o Does the individual exhibit any apparent physical or medical needs? Is the individual over or under weight, edentulous, continent? Does the individual have contractures, vision or hearing impairments?

o What adaptive devices/assistive devices are used? Does the individual use a hearing aid, glasses, plate guard , etc.? Does the device(s) appear to be used correctly?

o How does the individual move about in the environment? Does the individual use a walker, ambulate, move his own wheelchair, etc.?

o How does the person communicate? Does the person talk, use sign or a communication board, make facial expressions or behavioral responses? Do others appear to understand the person's communications?

o What is the person's level of social skill or behavior toward others? What types of interactions occur and with whom? Does the individual exhibit any maladaptive behaviors?

o What are the individual's observed skills relative to the activity or task observed? For example, if observed during dining, does the individual eat without assistance? What utensils

are used? Are applicable skills developed or encouraged during the activity, such as passing food, pace of eating, social conversations? Is the individual receiving any special diet?

- What level of assistance is provided by staff? What types of assistance are used - verbal prompts, gestures, hand over hand?

- Are there any individual needs that are not being addressed? Are staff aware of the observed needs? Is there a reason it is not being addressed?

4. Areas for Further Observation.--The surveyor will then identify areas to which to pay attention during other observations. Those areas may include any supports, interventions or skills that would be expected to occur consistently across settings or any apparent needs, concerns or discrepancies noted during the observation. For example, if the surveyor notes that the individual uses sign language for communication, do all staff working with the individual understand and use sign with him/her? Or if an individual is observed to have good gross motor skills, do staff feed the person or perform other tasks for him/her that your observation indicates the person could possibly do independently? Focus interviews and record review based on concerns, issues, inconsistencies and needs noted from these observation(s).

D. Documentation.--Record your observations. The optional individual observation worksheet (HCFA-3070I (10/95)) may be used. If your behavior or presence disrupts the activity being observed, wait five minutes before recording the observation.

VIII. TASK 4 - REQUIRED INTERVIEWS WITH INDIVIDUALS AND/OR FAMILY/ADVOCATE, AND DIRECT CARE STAFF

A. Purpose.--Individuals living in the facility, their families/guardians and advocates, and direct care staff are important sources of information about the receipt of active treatment on a daily basis. Interviews are conducted for two purposes: to determine how the individual perceives the services delivered by the facility, and to clarify information gathered during observations. Only interviews with the individuals, their family members/guardians, advocates, and direct care staff count toward the total number of required interviews (as reflected in the sample chart shown in Section 5B - Sample Size).

B. Interview Procedure.--Start with the individual in the sample and the people most closely associated with the individual's daily program implementation. Use the following hierarchy of sources, to the maximum extent possible, in the order shown:

- Individual;
- Families, legal guardian, or advocate;
- Direct care staff;
- Qualified mental retardation professional (QMRP) and/or professional staff; and
- Managers, administrators, or department heads

Determine from your observations and from the staff how the individual communicates with others. Also determine from the staff the extent of involvement of family members, guardians or advocates with the individuals in the sample. Based on this information, select the individuals from the sample with whom you will conduct more in-depth interviews. Select those individuals who will be able to communicate at least some basic information or those who have actively involved family members, guardians or advocates. Do not exclude from interviews individuals who use alternate means of communication, such as communication boards, sign language, and gestures. Most individuals are able to communicate in some manner. At a minimum conduct the number of in-depth interviews specified in Section V, Task 1B.

Attempt to obtain the required number of interviews first from individuals and then from family members, guardians or advocates. In the absence of individuals who are able to communicate and active significant others, interview the direct care staff person who works most closely with the individual in order to obtain the required number of in-depth interviews.

The questions and communication method will vary from person to person. For individuals who use a specialized communication method, attempt to begin the interview on a one to one basis. If you find you are unable to communicate with the individual, ask someone familiar with the person to assist you (e.g., a family member or a staff person.) For this individual, pay close attention to how the staff communicates with him or her. If the person uses sign language or a communication board, do staff understand and interact with the individual using the same method? If the person uses gestures, do staff take time to determine his or her needs?

Family members, guardians or advocates may be interviewed at the facility, at a location convenient to both the surveyor and the interviewee, or by telephone. All interviews should be conducted in private locations and scheduled at mutually agreed upon times in order to minimize disruptions to individual, family, or staff activities.

C. Content of In-depth Interviews.--Determine what the facility does to provide individualized services and supports; and how individuals and families participate in service planning and in making choices about matters important to them. Are individuals treated with respect and dignity? Does the facility attempt to help the person set and attain individual goals? Are there consistent opportunities for making choices? When a choice is not an option, how is the individual assisted to understand? For example, if a planned activity is to go to a restaurant for dinner, who chooses the restaurant? Staff or the individuals living in the facility? If one group of people does not want to go, how is this choice accommodated? Is the accommodation based on individual choice, staff convenience, or a reasonable justification if a choice is not an option?

See section D for suggested interview questions. Unless designated to be directed to a certain person, questions are relevant to whomever is being interviewed (individual, family member, advocate or staff person.) Modify the wording of the questions based on the person being interviewed (individual, family member, or staff) and on the communication skills of that individual. For example, you may discover that the person responds better to questions that can be answered "yes" or "no" than to open-ended questions. Be sensitive to signs that the individual is tiring or becoming uncomfortable and either end the interview or continue it at a later time if this occurs. It is not necessary to ask every question in the guide, but do try to ask at least one question from each topic area.

D. Suggested Interview Questions.--If you have not met the person before, begin the interview by explaining who you are and what your role is. To put the person at ease you may want to begin with some general conversation, e.g., about the weather or a special event coming up. At the end of the interview, if you think you may need to discuss or confirm personal information with staff or family, ask the person if it is OK to share that information.

1. Questions Related to Choice and Community Participation (W136, W147, W247):
   - o What sorts of things do you like to do for fun?
   - o Do you go out to activities or events in the community (like shopping, movies or church)?
   - o How often do you do this?
   - o How do you get there?

- Who chooses where you go?
- Do you go to visit family members or take vacations?
- Is there something you would like to do more often?

2. Questions Related to Personal Finances and Possessions (W126, W137):

- Do you earn money on your job (at your day program)?
- What do you like to buy with your money?
- Do you have enough money to buy the things you want or need?
- Does someone help you with spending or saving your money?
- When you go to the store, do you pay for items or does a staff person pay for them?
- Do you have enough clothes and shoes?
- Do you always have enough deodorant and toothpaste, etc.?
- What do you do if you need to buy something?

3. Questions Related to Personal Relationships and Privacy (W129-W130, W133, W143 -W148):

- Do you have family or friends who visit you?
- Does your family write to you or telephone you?
- Does someone help you read their letters/ call them on the phone?
- If you feel like being alone or spending private time with a friend or family where do you go?
- Do staff knock on your door before they come into the room?

For family member/advocate:

- How do you learn about things like the services your family member receives, an illness or a change in medication?
- Are there any restrictions on when you visit your family member or where you can go within the home?

4. Questions Related to Individual's and Family's Participation in the IPP Process (W209, W247):

- Do you go to (team) meetings with the staff where they talk about the services you get?
- Does your family/advocate come to these meetings?
- Were you asked if the date and time of the meeting were OK with you?
- What would you like to learn to do for yourself?
- Do the staff ask you what you want?
- Who chooses what you do?
- Does the staff listen to you and make changes based on what you want?

For staff:

- How do you communicate with this individual?
- What does (s)he like and dislike? How do you know that?

5. Questions Related to Service Delivery (W242, W249, W436):

- What help do you need from staff to dress, eat, bathe, etc?

- o Do you get any special therapy (e.g., speech or physical therapy)?
- o What new things are you learning to do?
- o What chores do you help with around the house?
- o Who helps you when you do not know how to do something?
- o What special equipment do you use?

6. Questions Related to Individual's Rights and Protections: W124-W125, W127, W153-W157, W127-W128, W263:

- o Who do you tell if you do not like something, or something is wrong?
- o Are there rules that everyone who lives here must follow?
- o What sorts of things are you allowed to do or not do?
- o How does the staff treat you?
- o Are staff loud?
- o Does staff yell, swear or hit?
- o Do you ever do things you are not supposed to do? What happens then?
- o Were you ever asked to give consent for any treatments or services?
- o Were you told the benefits, risks and alternatives?

7. Questions Related to Health Status (W322, W356):

- o How often do you see a doctor? A dentist?
- o Do you have any health problems?
- o Do you take any medicines? Do you know what they are for?

8. Wrap-up Questions:

- o Is there anything you especially like about living here? Anything you especially dislike?
- o Is there anything else you think I should know about what it is like to live here?

E. Interviews to Clarify Observations.--In the absence of finding appropriate interaction between staff and individuals during observations, it may be necessary to judge whether or not staff are knowledgeable about individual objectives and techniques for implementation of programs. If possible, interview staff following the interval in which the individual was observed with the particular staff member. (For example, if you have just observed Individual A engaging in stereotypical behaviors, ask: "Can you tell me what, if anything, you do when he rocks back and forth?") Ask questions that elicit information about how staff learn what to do with individuals across the spectrum of support and programming activities they are expected to perform. Ask professional staff questions to see if they know how to implement programs for an individual other than their professional discipline (e.g., how to carry through with a behavior program in the midst of communications training).

Ascertain whether the staff are competent to carry out the individual's choices and skill development activity. Is there evidence that programs are in fact being carried out throughout the individual's waking hours? Are interventions revised based on changes in the individual's progress toward goals? If staff cannot demonstrate the skills necessary to implement the individual's programs and choices, if interventions are not being carried out consistently, or if revisions to interventions do not occur, you have findings that active treatment is not being delivered.

E. Documentation.--Record each interview you conduct with individuals, staff, consultants, off-site day program staff, legal guardians, etc., in your personal notes or on the optional observation worksheet (HCFA-3070I). Include the following information in your notes for each interview:

- o Date and time of interview;
- o Job title and assignment at the ICF/MR;
- o Relationship to the individual or reason for the interview; and
- o Summary of the information obtained.

IX. TASK 5 - DRUG PASS OBSERVATION

Observe the preparation and administration of medications to individuals. With this approach, there is no doubt that the errors detected, if any, are errors in drug administration, not documentation. Follow the procedure in the interpretive guidelines at W369 for conducting the drug pass observation. Notes on observations of the drug pass may be recorded on Form HCFA-677 (LTC Medication Pass Worksheet) or in the surveyor's personal notes. The purpose of the review is to direct the facility's attention to assuring an error free drug distribution system and away from the paper processes that often do not represent actual errors in medication administration. For the purposes of this task, a "small" facility is one which houses 16 or fewer residents.

X. TASK 6 - VISIT TO EACH AREA OF FACILITY SERVING CERTIFIED INDIVIDUALS

A. Purpose.--By the end of the survey, visit each area of the facility serving certified individuals in order to:

- o Ensure that all areas of the facility (including those which are not represented by individuals in the sample) are providing services in the manner required by the regulations.
- o Assess generally the physical safety of the environment.
- o Assess that individual rights are proactively asserted and protected.

B. Protocol.--After individuals in the sample have been assigned to team members, review the facility's map or building layout. Assign members to visit each remaining residential and on-campus day program site prior to completing the survey. Insure that each area of the facility that is utilized by individuals has been visited. This visit may be done with or without facility staff accompanying you, as you prefer, and subject to their availability. Record your observations in your notes.

Converse with individuals, family members/significant others (if present), and staff. Ask open-ended questions in order to confirm observations, obtain additional information, or corroborate information, e.g., accidents, odors, apparent inappropriate dress, adequacy and appropriateness of training activities. Observe staff interactions with other staff members as well as with individuals for insight into matters such as individual rights and staff responsibilities.

XI. TASK 7 - RECORD REVIEW OF INDIVIDUALS IN THE SAMPLE

A. Introduction.--Do not spend an excessive amount of time looking at fine details in the record review of the selected sample. The purposes are to:

- o Verify the applicable information obtained from your observations and interviews;
- o Review revisions that have been made to the objectives; and
- o Verify that needed health and safety supports are in place.

Do not review in detail the written training programs that are developed for each individual unless you discover serious differences between the record and your observations and interviews. Review those parts of the record most relevant to your purposes as described below.

B. The Individual Program Plan (IPP).--Identify the developmental, behavioral, and health objectives the facility has committed itself to accomplish during the current IPP period. Identify what, if any, behavioral strategies (e.g., behavior modification programs, use of psychotropics) are being used with individuals in your sample. Determine what, if any, health or other problems might interfere with participation in program services.

C. Program Monitoring and Change.--Skim the most recent interdisciplinary team review notes to identify what revisions were made to the IPP. Determine whether revisions were based on objective measures of the individual's progress, regression, or lack of progress toward his/her objectives.

D. Health and Safety Supports.--Verify, either through the interdisciplinary team review notes or through the most recent nursing notes, that the individual has received follow-up services for any health or dental needs identified in the IPP and check the person's current drug regimen. For individuals with whom restrictive or intrusive techniques are used, verify that the necessary consents and approvals have been obtained.

If this information is consistent with your observations and interviews, conclude the record review. If discrepancies are found, conduct further observations or interviews as needed to verify your findings.

XII. TASK 8 -TEAM ASSESSMENT OF COMPLIANCE AND FORMATION OF THE REPORT OF ICF/MR DEFICIENCIES

A. General.--The Survey Report Form (HCFA-3070H) is composed during the pre-exit conference and contains the negative findings that contribute to a determination that an ICF/MR requirement is "not met." Meet as a team, in a pre-exit conference, to discuss the findings and make conclusions about the deficiencies, subject to additional information provided by facility officials. Review the summaries/conclusions from each task and decide whether further information and/or documentation is necessary. Ask the facility for additional information or clarification about particular findings, if necessary. Consider information provided by the facility. If the facility maintains that a practice in question is acceptable, request reference material or sources that support the facility's position.

B. Team Assessment of Compliance.--During the pre-exit conference, the survey team reviews each survey tag number reviewed during either the fundamental, extended or full survey, and comes to a consensus as to whether or not the facility complies with each requirement. The team reviews all data collected. For each standard determined to be not met, record salient findings on the HCFA-3070H. With the exception of the Life Safety Code Survey, compliance decisions are not made by individual surveyors when more than one surveyor has conducted the survey.

C. Analysis.--Analyze your findings relative to each requirement reviewed during either the fundamental, extended or full survey for the degree of severity, frequency of occurrence and impact on delivery of active treatment or quality of life. The threshold at which the frequency of occurrences amounts to a deficiency varies. One occurrence directly related to a life-threatening or fatal outcome can be cited as a deficiency. On the other hand,

a few sporadic occurrences may have so slight an impact on delivery of active treatment or quality of life that they do not warrant a deficiency citation.

The interpretive guidelines contain two types of guidance designed to assist the survey team in analyzing their findings and making consistent compliance decisions:

1. Facility Practice Statements.--The purpose of facility practice statements is to clarify the information that is relevant to specific requirements, and to increase the survey focus on outcomes for individuals. Facility practice statements are provided for those requirements which experience has shown, are difficult to interpret. The practice statements are not necessarily all inclusive, but rather represent the practices most commonly associated with compliance for specific requirements. Each facility practice statement relates directly to the language of the requirement to which it applies. Positive outcomes identified by the practice statements should be observed in operation in the facility during the survey. When the team's negative findings indicate that a practice is not present, a citation of the requirement may be appropriate, depending upon the frequency and the severity of those findings. Use the practice statements during the pre-exit conference to assist the team in analyzing negative findings and determining the appropriate requirement at which to cite negative findings. When stated in the negative, facility practice statements may form the basis for a citation on the HCFA-2567.

2. Condition Level Compliance Principles.--The purpose of the compliance principles is to assist in consistent decision-making about facility compliance at the Condition of Participation level. The primary focus of those decisions is placed on the outcomes to the individuals and their actual experiences of daily life. At each Condition of Participation, the guidelines contain compliance principles which identify those outcomes that must be present in order for the Condition to be found "met," and those outcomes that indicate the Condition is "not met." The compliance principles are based on the requirements which fall under the Condition. This guidance is NOT to replace professional surveyor judgement. It is possible that the surveyor may encounter a situation which is not covered by the compliance principles, however, such instances are expected to be rare. In the event the survey team makes a determination that the Condition is "not met," and the situation causing that determination is not identified in one of the "not met" compliance principles, notify HCFA's Central Office in writing within 10 days after the completion of the survey for purposes of review, possible dissemination to other surveyors, and to ensure consistency within the survey process.

Some of the compliance principles for the Conditions of governing body, facility staffing and physical environment reference other Conditions. Governing body, facility staffing and physical environment tend to address organizational processes which support the provision of active treatment, protection of rights and adequate health and dietary services. Therefore, the governing body, facility staffing and physical environment Conditions are usually "met" unless it is first determined that there are serious deficiencies in services or protections which fall under one or more of the other areas.

After the survey team reviews its positive and negative findings for the requirements within a particular Condition of Participation and determines which of those requirements are deficient, examine the findings for that Condition as a whole. When analysis of these findings leads the team to conclude that each of the "met" compliance principles for that Condition is present, then the facility is in compliance with that Condition. When analysis

of the standard level deficiencies viewed as a whole, leads the team to conclude that one or more of the "not met" compliance principles for that Condition is present for one or more individuals or situations, consider the frequency and the severity of the negative finding(s) in relation to the applicable "not met" compliance principle(s) in order to determine whether Condition level noncompliance is warranted.

D. Composing the Report of ICF/MR Deficiencies (HCFA-3070H/(10/95)).--
During the pre-exit conference, the survey team records on the HCFA-3070H those requirements that are determined to be deficient and the findings which support that determination. Write the deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand the aspect(s) of the requirement(s) that is (are) not met. Do not delve into the facility's policies and procedures to determine or speculate on its root cause, or sift through various alternatives to prescribe an acceptable remedy. Indicate on the HCFA-3070H the data prefix tag, followed by a summary of the deficient facility practice(s). Briefly identify the supporting findings for each deficiency (i.e., transfer to the HCFA-3070H the identifier numbers of all individuals to whom the deficient practice applies.) It is not necessary to write a full description of the findings on the HCFA-3070H since they will be described in more detail on the completed Statement of Deficiencies (HCFA-2567). It is necessary to complete the HCFA-3070H for each survey because the HCFA-3070H is the only document in which the survey team's recommendations for deficiencies are recorded (which may be changed later on the final HCFA-2567 as a result of supervisory review) and because not all individual examples may be used on the HCFA-2567. Instructions for the HCFA-3070H are found on page J-18.6.

Alternatively, when the survey team enters its findings directly into a computerized system such as Automated Survey Processing Environment during the pre-exit conference, the statement of deficiencies (HCFA-2567) that is generated onsite at the facility may be substituted for the HCFA-3070H. The HCFA-2567 generated onsite then must contain the information required for the HCFA-3070H and must be clearly marked "DRAFT - SUBJECT TO STATE AGENCY REVIEW" on each page.

XIII - ADDITIONAL SURVEY REPORT DOCUMENTATION (FOR THE FILE)

Upon the completion of each survey, the team leader completes the following additional documentation. This information remains at the survey agency with the HCFA-3070G-H (10/95) in the official file:

A. Summary Listing of all ICF/MR Individuals Comprising the Survey Sample (include any additional individuals added to the sample).--At a minimum, identify:

- The name or Medicaid number of each individual chosen to be part of the sample;
- Any individual identifier codes used as a reference to protect the individual's confidentiality; and
- The reason for including the individual in the sample (e.g., "Random Program Audit," "Discharge," "New Admission," "Death," "Abuse Investigation", "Drugs to Control Behavior"). This listing serves as a future reference to any individual identifiers recorded in surveyors' notes, the HCFA-3070G-I, and the HCFA-2567.

B. Description of the Representative Sample Selection.--At a minimum, identify, at the time of the survey:

- How the sample was selected;

o What was the percentage occurrence of each functional level of mental retardation in the facility's overall population;

o The distribution of the individuals in the sample across the facility's living units;

o The number of people in the sample;

o The number, if any, of individuals substituted in the sample, and the reason; and

o Any other characteristic of individuals served that was specifically introduced into the sampling process and the reason.

C. Summary of Individual Observations.--Include all individual observation worksheets (HCFA-3070I) and any surveyor notes containing information regarding observations. These notes should include the dates, locations, and starting and ending times for each observation.

D. Summary of Interviews.--Include all surveyor notes containing information obtained during interviews with individuals, families, guardians, direct care staff, QMRPs, professional staff or consultants, administrators and managers, and others. These notes should identify the person interviewed by name or position, and date and time of interview.

E. Drug Pass Worksheets (HCFA-677) or Surveyor Notes of the Drug Pass Observation

F. Other Relevant Facility Data.--Include other salient data used in support of the survey findings with the HCFA-3070G-H (10/95) (e.g., photographs, affidavits). The survey agency's documentation of the justification for the decision to conduct a full survey must be maintained in the survey agency's file.

XIV. COMPLETING THE REVISED HCFA-3070-G-I (10/95) ICF/MR SURVEY REPORT FORM (SRF)

Part 1 (3070G): This is the cover sheet for the ICF/MR SRF which summarizes data relative to: facility characteristics; description of the individual population served; special needs represented by that population; and essential characteristics of the survey conducted. Portions of this information are entered into the Onsite Survey and Certification Automated Reporting (OSCAR) System and used to review trends about the ICF/MR program nationwide.

General Instructions:

1. Complete all portions of Part 1 onsite, preferably during the first day of the survey. Work with the facility to complete the form according to these instructions and to ensure accurate information is obtained prior to leaving the facility.
2. If a number is requested (e.g., No. of beds, No. of individuals), and the answer is NONE or ZERO, enter a "O" in the space provided.

3. If a box is provided to "check one" of the answers provided, enter a check mark.
4. Abbreviations used: "CEO" means Chief Executive Officer; "QMRP" means Qualified Mental Retardation Professional; "MR" means mental retardation; "No." means number.
5. Regulatory references on the form refer to regulations found in the Code of Federal Regulations, and refer to regulations applicable to ICFs/MR.
6. Review all portions for accuracy prior to leaving the facility.

Specific instructions:

Blocks 1-10, 13-14: Enter identifying data, as requested.

Block 11: Enter the dates of the first and last days of the survey (even if there is a break in survey days).

Block 12: Enter the number describing the ownership/control type in the box marked "W6." If "other" best describes the facility, specify the other type on the space provided.

Blocks 15 (A-M): (Col. 1): Enter the No. of disciplines that best describe your team's composition. If a surveyor has multiple areas of expertise (e.g., a nurse surveyor who is also a dietitian), include each discipline of expertise. (Col. 2) Enter the No. of disciplines represented on the team which also qualified as a QMRP (as per 42 CFR 483.430(a)(1)(2)(i)-(iii) and 42 CFR 483.430(b)(5) of the ICF/MR Conditions of Participation.

Blocks 15 (N-O): Enter the number, as requested.

Blocks 16 (A-B): A "Yes" indicates that the CEO directs not only the activities of the ICF/MR, but also those of another residential services program (e.g., another ICF/MR; another Medicare/Medicaid Provider that serves persons with MR regardless of funding source). A "No" indicates that the CEO of the ICF/MR does not direct the activity of another residential services program for persons with MR. If "Yes" was indicated for 16A, identify the name, address and CEO of the larger organization or agency in 16B (could be the same information for this ICF/MR in Block 7.) Enter the total bed capacity of all residential services for which the CEO is directly responsible (including the ICF/MR bed capacity) in "W14". Do not include beds for which the CEO is indirectly responsible. (For example, in some States the CEO of a State-operated institution is also indirectly responsible for all beds in a region, including those operated by private providers within that region. Do not include beds directly operated by another agency or organization for the purposes of

W14.) Enter the total No. of individuals residing in the beds (including ICF/MR individuals) in "W15."

Block 16C: Enter the No. as requested.

Block 16 D: A "Yes" indicates that this ICF/MR (i.e., the beds under this provider number) is the only house or apartment at the address stated in Block 2 and is located in close proximity to other houses or apartments occupied by people who are not disabled. A "No" indicates that there is other bed capacity to provide residential services to persons with disabilities at the address stated in Block 2 or that this ICF/MR is surrounded by other buildings or residential units serving people with disabilities.

Block 16 E: Enter the No., as requested.

Block 16 F: Enter the total No. of discrete units. If the ICF/MR encompasses several bldgs, count the total No. of discrete living units within all buildings.

Block 16 G: List the ages of the youngest individual in W20 and oldest in W21.

Block 16 H: Each day's program site included in this number should be located off the grounds or campus of the ICF/MR. Any individual going to this program should be scheduled to attend regularly (at least 3 hrs.a day, 2-5 days a wk.). If the day program provides 2 or more programs at the same address, for purposes of this item, consider it one site.

Blocks 17 (A-D): Enter the full time equivalents (FTEs) for each category listed. For 17A, include only staff who provide direct care services to individuals at their living units. Include direct care supervisors only if they are also responsible to provide direct care as part of their duties. (See 42 CFR 483.430(d).) For 17D, include <u>all</u> personnel, including the No. of direct care and licensed nursing personnel, as well as professional and support staff employed by the facility. To determine FTEs: add the total No. of hrs. worked the week prior to the survey, by all employees identified in each
category of 17 (A-D); divide this No. by the No. of hrs. in the standard work week. Express FTEs to the nearest quarter decimal (i.e., ".00", ".25", ".50", and ".75").

Block 18 A: Enter the No. of individuals in the total sample (i.e., the representative sample and any other individuals added to the sample for other reasons.)

Block 18 B: Enter the No. of sites visited in which observations of individuals in the sample were completed.

Blocks 20 (A-L): <u>INDIVIDUAL CHARACTERISTICS</u>: The last date of the survey is the date by which age is determined. The term "Total" No. refers to the No. of ICF/MR individuals fitting the

characteristic listed who are currently living in the facility.

20 A (1): Enter the total No. of individuals within each age group regardless of sex.

Blocks 20 A (2): Enter the No. of individuals by sex and the total. The total should equal the No. entered in 20 (A)(1), Total (W33).

Blocks 20 (B-C): Enter the total No. of individuals by each characteristic requested; and the total. Count individuals with more than one disability in every applicable column. Use the following definitions:
Autism is a diagnosis whereby the individual exhibits extreme forms of self-injurious, repetitive, aggressive, or withdrawal behaviors; extremely inadequate social relationships; or extreme language disturbances.

Cerebral Palsy is a diagnosed condition whereby gross and fine movements and speech clarity of the individual may be impaired but performance of activities of daily living is functional; or, the individual is unable to perform adequately activities of daily living such as walking, using hands, or using speech for communication.

Mental retardation levels (mild, moderate, severe, and profound) are described in the American Association on Mental Deficiency's Manual on Classification in Mental Retardation (1983 edition).

Nonambulatory means unable to walk independently.

Mobile nonambulatory means unable to walk independently, but able to move from place to place with the use of such devices as walkers, crutches, wheelchairs, and wheeled platforms.

Nonmobile means unable to move from place to place.

Epilepsy means a neurological disorder characterized by seizures of motor and sensory movements.

Hard of Hearing means able to hear speech, including with amplification.

Deaf means unable to hear speech, even with amplification.

Impaired vision means able to see objects, with correction.

Blind means unable to see objects.

Blocks 20 (D-K): Enter the total No. of ICF/MR individuals who have the following care needs or characteristics: Medical Care Plan (i.e., requires 24 hour licensed nursing care as defined at
42 CFR 483.450(a)(2)); Drugs to Control Behavior (42 CFR 483.450(b)(1)(iv)(C); Restraints
(42 CFR 483.450(b)(1)(iv)(B);Time-out rooms (42 CFR

483.450(b)(1)(iv)(A); Application of Painful or Noxious Stimuli (42 CFR 483.450(b)(1)(iv)(D); Attend Off-Campus Day Programs; Court Ordered Admissions; and the No. Over Age 18 with a Legally Appointed Guardian.

Block 20 L:

If the facility or you believe that a particular individual or program characteristic that describes the population has not been requested on this form, identify it, programs provided, etc., in the space provided. Enter the total Nos. of individuals having this characteristic.

Part 2 (3070-H):

REPORT OF DEFICIENCIES

Use this part in conjunction with the regulation text and interpretive guidelines. Include basic information on non-compliance. Complete the report during the pre-exit conference for all surveys. Record all deficiencies found during the survey. Sign it, certifying that all other facility requirements not documented as deficiencies, are in compliance.

Evaluate each discrete requirement identified by a tag number in the ICF/MR Interpretive Guidelines. For each identified deficiency:
- o In the first column, identify the data tag number;
- o In the second column, write the standard number. If it is a Condition of Participation, enter "CoP" below the standard number.
- o Identify the deficient facility practice, findings and evidence in the "Comments" column.
- o Draw horizontal lines to separate identified tag numbers.
- o Use as many sheets as needed.
- o Each surveyor must sign the appropriate certifying statement on the last page of Part 2.

Part 3 (3070-I):

INDIVIDUAL OBSERVATION WORKSHEET

Part 3 of the SRF is an optional worksheet that may be used to record and structure observations so that individual data relative to compliance with the statutory active treatment requirement are available for analysis and retrieval. This is completed for each observation as follows:

Heading: Enter requested names, locations, codes, times and dates. Enter "individual codes" only if individuals in the sample are present.

Column 1 - Time: Enter the time of discrete observations or consecutive time intervals.

Column 2 - Observation: Include the information specified in Section V-B of this Appendix for each observation (e.g., number of individuals; number of staff; activity in progress).

INTERPRETIVE GUIDELINES: TABLE OF CONTENTS

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TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§440.150 Intermediate care facility services, other than in institutions for mental diseases.	
W100	(c)"Intermediate care facility services" may include services in an institution for the mentally retarded (hereafter referred to as intermediate care facilities for persons with mental retardation) or persons with related conditions if- - (1) The primary purpose of the institution is to provide health or rehabilitative services for mentally retarded individuals or persons with related conditions; (2) The institution meets the standards in Subpart E of Part 442 of this Chapter; and (3) The mentally retarded recipient for whom payment is requested is receiving active treatment as specified in §483.440.	§440.150(c) FACILITY PRACTICES: The facility is in compliance with the Condition of Participation at W195, i.e., individuals are in need of and receiving active treatment. §440.150(c) GUIDELINES: The statutory and regulatory use of the word "institution" includes settings that serve four or more people with mental retardation and/or related conditions. See §435.1009 for definition of "persons with related conditions." The presence or absence of an individual requiring a medical care plan, as defined at W320, is not salient in the determination of whether a facility is eligible to participate in the ICF/MR program.
*	W101 is reassigned to §483.410(e). Section 442.251, the standard which requires that facilities meet the requirement for a State license, is redesignated to §483.410(e) and W101 is reassigned as well to afford a sense of continuity.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
W102	§483.410 Condition of participation: Governing body and management.	§483.410 COMPLIANCE PRINCIPLES: The Condition of Participation of Governing Body is met when each of the other Conditions of Participation are also met. The Condition of Participation of Governing Body is not met when: o One or more of the other 7 Conditions of Participation have first been determined to be not met, and the governing body has failed to take action that identifies and resolves systemic problems of a serious and recurrent nature; or o The facility has been denied any license or approval required by Federal, State or local law by the authority having jurisdiction for that law.
	(a) Standard: Governing body.	
W103	The facility must identify an individual or individuals to constitute the governing body of the facility.	
	The governing body must- -	
W104	(1) Exercise general policy, budget, and operating direction over the facility;	§483.410(a)(1) FACILITY PRACTICES: The governing body provides, monitors, and revises, as necessary, policies and operating directions which ensure the necessary staffing, training resources, equipment and environment to provide individuals with active treatment and to provide for their health and safety. §483.410(a)(1) GUIDELINES: The responsibility for direction includes areas such as health, safety, sanitation, maintenance and repair, and utilization and management of staff, especially when problems in these areas are of a serious or recurrent nature. Condition level deficiencies (other than the Governing Body Condition) or repeat, pervasive patterns of deficiencies at the Standard level may be an indication that the governing body is not providing sufficient operating direction over the facility. When a pattern of serious or repeated deficiencies is identified during the survey, interview the administrator or review the minutes of governing body meetings, if available, to determine whether or not the governing body has identified and addressed the problem. Staff who have been trained, but are not implementing programs or are inappropriately deployed (e.g., there are enough staff but they are assigned to duties like record keeping which prevents them from delivering needed services), may indicate a failure of the governing body to adequately direct the staff's activities.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
W105	(2) Set the qualifications (in addition to those already set by State law, if any) for the administrator of the facility; and	
W106	(3) Appoint the administrator of the facility.	
	(b) Standard: Compliance with Federal, State and local laws.	
	The facility must be in compliance with all applicable provisions of Federal, State and local laws, regulations and codes pertaining to	§483.410(b) FACILITY PRACTICES: The facility has received no adverse action(s) by the Federal, State or local authority having jurisdiction in these areas. The facility is in compliance with W101, W105, W153, W156, W170, W265, W328, W345, W370 and W374. §483.410(b) GUIDELINES: Licenses, permits, and approvals of the facility must be available to you upon request. Current reports of inspections by State and/or local health authorities are on file, and notations are made of action taken by the facility to correct deficiencies. Some State or local laws are more stringent or prescriptive than the Federal Medicaid requirement on the same issue. Failure of the facility to meet a Federal (i.e., non-Medicare or Medicaid), State or local law may be cited only when the authority having jurisdiction (AHJ) has both made a determination of non-compliance and has taken a final adverse action. An adverse action is defined as any procedure that goes beyond the approval of a plan of correction, such as a civil money penalty, ban on admissions, denial of payment, or loss of license, and is not under appeal by the provider. The AHJ is the public official(s) having authority to make a determination of noncompliance, and is responsible for signing correspondence notifying the facility of the adverse action. If the you believe you have identified a situation indicating the provider may not be in compliance with a Federal, State or local law, refer that information to the AHJ for follow-up action. If a final adverse action results, then the facility could be found to not meet §483.410(b).
W107	o health,	
W108	o safety, and	
W109	o sanitation.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	Standard: Client records.	
W110	(1) The facility must develop and maintain a recordkeeping system that includes a separate record for each client and	
W111	that documents the client's health care, active treatment, social information, and protection of the client's rights.	§483.410(c)(1) GUIDELINES: The structure and content of the individual's record must be an accurate, functional representation of the actual experience of the individual in the facility. This should be identified through interviews with staff and, when possible, with individuals being served, as well as through observations. The regulations do not specify that all information about an individual be located in the individual program plan (IPP) document, only that information explicitly identified in the regulations. The regulations do not prescribe the manner, form or where in the individual's record this information is to be recorded.
W112	(2) The facility must keep confidential all information contained in the clients' records, regardless of the form or storage method of the records.	§483.410(c)(2) FACILITY PRACTICES: The facility has in place sufficient safeguards to ensure that access to all information regarding individuals is limited to those individuals designated by law, regulation, policy, or duly authorized consent as having a need to know. No unauthorized access or dissemination has occurred. §483.410(c)(2) GUIDELINES: "Keep confidential" means safeguarding the content of information including video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian, and consistent with the advocate's right of access, as required in the Developmental Disabilities Act. Facility staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to the individual. Confidentiality applies to both central records and information kept at dispersed locations. If there is information considered too confidential to place in the record used by all staff (e.g., identification of the family's financial assets, sensitive medical data), it may be retained in a secure place in the facility (e.g., social worker's locked desk). A notation must be made in the record of the location of confidential information (e.g., "Family information is available from the social worker"). The sharing of individual specific information with members of the "specially constituted committee" required by §483.450(f)(3), who are not affiliated with the agency, does not violate an individual's right to have information about him or

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		her kept confidential. The committee needs to know relevant information to function properly. The facility is allowed the flexibility to work out arrangements with its members to maintain confidentiality.
W113	(3) The facility must develop and implement policies and procedures governing the release of any client information, including consents necessary from the client, or parents (if the client is a minor) or legal guardian.	§483.410(c)(3) FACILITY PRACTICES: The facility has developed the required policies and procedures and follows them. Release of any personally identifiable information does not occur unless appropriate consent(s) is obtained prior to the release. §483.410(c)(3) GUIDELINES: Although one facet of the requirement is that the facility must decide how this is to be accomplished (i.e., policies and procedures), the surveyor's primary focus should be on the second part of the requirement, i.e., the facility's implementation or "outcome" that consent is obtained prior to the release of any individual information (e.g., records, photographs, interviews, or other means of exposure to public view or identification). The following guidance is provided to assist in determining whether informed consent for release of information is adequate: 1. Was the confidential information to be released specifically identified? 2. Was the person or agency to whom the information was to be released identified to the consenting party? 3. Was the consent time-limited (i.e., include the date the consent was given, and the date which the specific consent would be invalid)? 4. Was the person giving consent legally able to give consent? Information regarding an individual's HIV status may not be released without specific consent and may not be in the record if that consent has not been given. Staff are expected to use universal precautions when dealing with all individuals, therefore, it is unnecessary to routinely share information about HIV status with all staff. Under some conditions, knowledge may be shared with those directly involved in the care of infected persons. Surveyors should be familiar with State law requirements.
W114	(4) Any individual who makes an entry in a client's record must make it legibly, date it, and sign it.	§483.410(c)(4) GUIDELINES: In cases in which facilities have created the option for an individual's record to be maintained by computer, rather than hard copy, electronic signatures are acceptable. Given the large number of entries that are made in individual's records, this requirement is cited only when a systemic problem is identified.

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W115	(5) The facility must provide a legend to explain any symbol or abbreviation used in a client's record.	
W116	(6) The facility must provide each identified residential living unit with appropriate aspects of each client's record.	§483.410(c)(6) FACILITY PRACTICES: The staff of the residential living unit has, and can access, all information which is relevant to implementing individual program plans, appropriate care of, interaction with, and provision of services for the individual. §483.410(c)(6) GUIDELINES: "Appropriate" means those parts of each individual's record most likely (or known) to be needed by the residential staff to carry out the individual's active treatment program in the unit, to alert staff to health risks and other aspects of medical treatment, to support the psychosocial needs of the individual, and anything else necessary to the staff's ability to work on behalf of the individual.
	(d) Standard: Services provided under agreements with outside sources.	
W117	(1) If a service required under this subpart is not provided directly, the facility must have a written agreement with an outside program, resource, or service to furnish the necessary service, including emergency and other health care.	§483.110(d)(1) GUIDELINES: Federal statute (P.L. 94-142) requires all school-aged children to receive a free and appropriate school education. Therefore, a written agreement between ICFs/MR and public schools is not necessary.
	(2) The agreement must- -	
W118	(i) Contain the responsibilities, functions, objectives, and other terms agreed to by both parties; and	
W119	(ii) Provide that the facility is responsible for assuring that the outside services meet the standards for quality of services contained in this subpart.	

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		§483.410(d)(2)(ii) GUIDELINES: Outside providers of day services would not have to meet certain requirements relating to physical environment under §§483.470 (a)-(g), (j), and (k) unless that source also provides living quarters for ICF/MR individuals. Outside sources must, of course, meet any applicable State and local requirements. The facility's responsibility includes assuring that any restrictive techniques proposed for use by outside service providers are used only when warranted and with the required safeguards and approvals.
W120	(3) The facility must assure that outside services meet the needs of each client.	§483.410(d)(3) FACILITY PRACTICES: Outside service providers meet the needs of each individual as identified by the interdisciplinary team. Programs and services are coordinated/integrated and consistent with those provided by the facility. §483.410(d)(3) GUIDELINES: "Assure" means that the facility's staff actively participate with staff in outside programs in the assessment process and in development of objectives and intervention strategies. For example, if a public school is implementing a manual communication system with an individual, the direct care staff in the individual's living unit should have instructions to implement the program in the residential environment. Likewise, if the facility is implementing a behavior management program for the individual, it should be shared with and implemented as needed by the outside program. This communication is often difficult, but nevertheless essential to the provision of active treatment. §483.410(d)(3) PROBES: Is there evidence of shared communication, program planning and implementation, and problem solving? Is there a relationship among the objectives, data, techniques, etc., within the programs or services delivered? Does the facility periodically observe services that are provided by the outside resource?
W121	(4) If living quarters are not provided in a facility owned by the ICF/MR, the ICF/MR remains directly responsible for the standards relating to physical environment that are specified in §483.470(a) through (g), (j) and (k).	§483.410(d)(4) GUIDELINES: Even though the facility's premises may be rented from a landlord, the facility must ensure that the requirements for physical environment are met, either through arrangement with the landlord or through the facility's own services.

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	(e) Standard: Licensure.	
W101	The facility must be licensed under applicable State and local law.	§483.410(e) FACILITY PRACTICES: The facility has a current, valid State license when required under State law.

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W122	§483.420 Condition of participation: Client protections.	§483.420 COMPLIANCE PRINCIPLES: The Condition of Participation of Client Protections is met when: o Individuals are free from abuse and neglect; o Individuals are free from unnecessary drugs and restraints; and o Individual freedoms are promoted (e.g., individuals have choice and opportunities in their money management, community involvement, interpersonal relationships, daily routines, etc.). The Condition of Participation of Client Protections is not met when: o Individuals have been abused, neglected or otherwise mistreated and the facility has not taken steps to protect individuals and prevent reoccurrence; o Individuals are subjected to the use of drugs or restraints without justification; or o Individual freedoms are denied or restricted without justification (e.g., systemic lack of privacy, of freedom of access to the community or to other individuals, in use of personal possessions and money, etc.). §483.420 GUIDELINES: A citation of W127 or W150, which require that individuals are not subjected to verbal, sexual, or psychological abuse or punishment, is sufficient justification that the facility has failed to comply with the most fundamental of protections and, therefore, does not comply with this Condition of Participation.
	(a) Standard: Protection of clients' rights. The facility must ensure the rights of all clients. Therefore, the facility must- -	§483.420(a) GUIDELINES "Ensure" means that the facility actively asserts the individual's rights and does not wait for him or her to claim a right. This obligation exists even when the individual is less than fully competent and requires that the facility is actively engaged in activities which result in the pro-active assertion of the individual's rights, e.g., guardianship, advocacy, training programs, use of specially constituted committee, etc.
W123	(1) Inform each client, parent (if the client is a minor), or legal guardian, of the client's rights and the rules of the facility;	§483.420(a)(1) FACILITY PRACTICES: Individuals and their representatives, if applicable, are aware of the individual's rights and the rules of the facility. Information has been provided to the individual and their representatives, if applicable, in terms and language they understand. Individuals who are unable to understand their rights have family members, legal guardians or advocates who are involved in protection of their rights. §483.420(a)(1) GUIDELINES: The obligation to inform requires that the facility present information in a manner and form which can be understood, e.g., use of print materials, specialized programs to inform individuals who are deaf or blind, use of interpreters, etc.

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		§483.420(a)(1) PROBES: How does the facility determine if an individual can or cannot understand his/her rights? How does the facility inform staff, individuals, parents and/or guardians , or non-English speaking individuals of rights (e.g., use of printed materials, specialized programs to inform deaf and/or blind individuals, informal conferences)? To what extent has the question of advocacy been raised if individuals do not have family members? If individuals have family members who do not wish to have contact made with them? If the individual does not want the family to participate in decision making? What manner of assistance is provided once a decision is made that an individual has a need for advocacy, guardianship, or protective services?
W124	(2) Inform each client, parent (if the client is a minor), or legal guardian, of the client's medical condition, developmental and behavioral status, attendant risks of treatment, and of the right to refuse treatment;	§483.420(a)(2) FACILITY PRACTICES: Individuals and their representatives, if applicable, are aware of the individual's medical condition and treatment, therapies, services and other treatment or prescribed approaches being received, the reason for their use, as well as any risks involved in those treatments or approaches. Individuals and their representatives, if applicable, understand the alternatives to proposed treatments, that they can refuse treatment, and the possible consequences/ alternatives to such refusal of treatment. §483.420(a)(2) GUIDELINES: The term "attendant risks of treatment" refers to all treatment, including medical treatment. An individual who refuses a particular treatment (e.g., a behavior control, seizure control medication or a particular intervention strategy) must be offered information about acceptable alternatives to the treatment being refused, if acceptable alternatives are available. The individual's preference about alternatives should be elicited and considered in deciding on the course of treatment. If the individual also refuses the alternative treatment, or if no alternative exists to the treatment refused, the facility must consider the effect this refusal may have on other individuals, the individual himself or herself and the facility, and if it can continue to treat the individual consistent with these regulations. Thus, every effort must be made to assist the individual to understand and cooperate in the legitimate exercise of the IPP. An individual being considered for participation in experimental research must be fully informed of the nature of the experiment (e.g., medication, treatment) and understand the possible consequences of participating or not participating. The individual's written consent must be received prior to participation. For an individual who is a minor or who has been adjudicated as incompetent, the written informed consent of parents of the minor or the legal guardian is required. The determination as to whether the individual was sufficiently "informed" is based on

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		the following: 1. Was the individual aware of the proposed program or treatment, the procedures to be followed, and the identification of the person who will perform the treatment activity? 2. Was the individual aware of the intended outcome or benefits of the proposed program or treatment? 3. Was the individual aware of the possible risks, including side effects and attendant discomfort of the proposed program or treatment, and the steps to be taken to minimize risk? 4. Was the individual aware of the ramifications if he or she decided not to participate, and of the alternatives to the proposed activity, particularly alternatives offering less risk or adverse effects? 5. Did the individual participate voluntarily? Did the individual have the opportunity to have questions about the activity answered? 6. Was the information about the activity presented in language that could be readily understood by the individual? Additionally, for experimental, invasive or potentially harmful treatment, activities or procedures for which written informed consent is recommended, if not otherwise required by State or Federal law: 1. Was the consent time-limited (i.e., include the date the consent was signed and the date it becomes invalid)? 2. Did the individual realize that consent to participate could be withdrawn at any time without risk of punitive action? 3. Was the person who gave consent the legally appropriate party to do so for the individual? §483.420(a)(2) PROBES: How does the facility inform the individual/parent/guardian of the individual's condition, and of other significant events (e.g., through written correspondence, phone calls, informal conferences, in native language, in a timely manner)? Is there correspondence in the record informing the appropriate guardian of the individual's condition? Is there evidence of informed consent when needed? Are alternative treatment procedures made available for those who refuse specific treatment? What kinds of treatments do individuals refuse (if any)? Why? How does the facility respond to refusals? How does the facility ensure that the concept of informed consent has been taught to individuals, including the ramifications of refusal of treatment? Is there evidence that appropriate people are informed of benefits and risks of treatments, including psychoactive drugs?

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		What does the facility do when individuals show consistent patterns of refusal of treatments or programs?
W125	(3) Allow and encourage individual clients to exercise their rights as clients of the facility, and as citizens of the United States, including the right to file complaints, and the right to due process.	§483.420(a)(3) FACILITY PRACTICES: Individuals are taught and encouraged to claim and exercise their rights. A personal advocate or legally sanctioned surrogate decision-maker has been identified, when appropriate, and is encouraged to assist/support the individual in exercising these rights. Individuals and their representatives, if applicable, are aware of how to file a complaint and are free from reprisal when they do so. Individuals have the opportunity to register to vote and are taught skills to assist them in exercising this right. §483.420(a)(3) GUIDELINES: The facility must ensure protection of the individual from any form of reprisal or intimidation as a result of a complaint or grievance reported by an individual. As long as there are no decisions or circumstances which require action by a legally- appointed surrogate, a spokesperson or advocate could assist the individual in exercising his or her rights as a citizen of the United States and as a person residing in the facility. Some examples might include assisting the individual to express his/her needs, wants and interests, to utilize community resources or to file a complaint. A spokesperson might also express opinions regarding situations in which consent by the beneficiary, parent of a minor, or legal guardian is required in order to bring to the attention of the facility potential concerns or problems. The extent to which any person can act on behalf of another individual who has been assessed as needing a guardian, however, is entirely dependent upon the needs of the individual client and upon the laws and regulations of the State in which that individual resides. The facility and surveyor must be familiar with the laws and regulations of the State in which the facility is located. It is inappropriate for the facility to unofficially delegate the individual's rights to others (e.g., parents, family, advocacy groups, etc.) To the extent that the individual is able to make decisions for himself or herself, it is inappropriate to delegate the person's rights to others. Individuals who need guardianship or advocacy, and do not have this need addressed, are not prepared to exercise their rights as citizens of the United States. The facility's failure to ensure guardianship or advocacy for those who need it should be cited. Further deficiencies may also be cited under W123, W124, W143, and W263, depending upon the survey findings.

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		§483.420(a)(3) PROBES: How are individuals prepared to exercise their rights? Are provisions made for all individuals to assert their rights including those with mobility, sensory and communication impairments? Can staff explain individual rights and how they facilitate individual exercise of rights? Do individuals use advocacy systems? Are there established individual grievance procedures? Are advocates given access to the individual and his/her records, as appropriate, consistent with the Developmental Disabilities Assistance and Bill of Rights Act, as amended? Are rights that are modified or limited specific, general, or blanket? Are they reviewed to ensure continued appropriateness to the individual? What ways show that individuals assert their rights (e.g., do they vote, self-advocate, participate in self-governance council, participate in citizenship training, participate in community political activities)? What type of complaints do individuals report (if any) and how well does the facility respond? When interviewing individuals, do they describe situations which demonstrate the exercising of their rights? On what basis does the facility accept, or not accept, an individual's informed choice? In what manner is due process ensured? How does the team fit into this process?
W126	(4) Allow individual clients to manage their financial affairs and teach them to do so to the extent of their capabilities;	§483.420(a)(4) FACILITY PRACTICES: Individuals receive instruction (either as part of a formal program or a more general, informal series of activities) on handling their money which is geared to the individual's functional level. Individuals have opportunities to hold and manage their own money to the maximum extent of their capabilities. §483.420(a)(4) GUIDELINES: Since the use of money is a right, determine if the facility demonstrated, based on objective data, that the individual was unable to be taught how to use money before the decision was made to restrict that right.

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		§483.420(a)(4) PROBES: How many individuals does the facility report manage their own funds? Through interview and observation of staff and individuals served, are there individuals who are able to manage their own money with assistance, if needed? Are individuals allowed to spend funds as they choose? Are there spending opportunities? Do they have cash? Does staff, in fact, make financial decisions for use of individual funds which the facility reports are managed by the individual? Do staff work closely with particular individuals to participate in decisions about spending their money? For those individuals who manage their financial affairs, are they knowledgeable of their income source and amount? What evidence is manifest by individuals that they know what to do with personal finances? To what extent do individuals know how to conduct bank transactions? How are individuals paid? Cash? Check? Vouchers? Tokens?
W127	(5) Ensure that clients are not subjected to physical, verbal, sexual or psychological abuse or punishment;	§483.420(a)(5) FACILITY PRACTICES: No patterns, isolated incidents, unexplained functional regression, or other evidence of physical, verbal, sexual or psychological abuse or punishment posing a serious and immediate threat to individuals are present, are likely to occur, or have occurred without corrective action. The following situations constitute evidence of abuse: 1. Individuals are involved in serious incidents (e.g., injuries, elopements) caused by one or more of the following: o Insufficient or incompetent supervision, regardless of the location of the incident; o Program structure not meeting individual needs; o Failure to intervene when indicated (i.e., neglect); o Active treatment strategies that have proven to be ineffective and have not been revised to meet individual needs; o Placement in an unsafe environment; o Monitoring systems that are absent or are inadequate to prevent such incidents; or o Placement with aggressive/assaultive individuals in the absence of adequate supervision. 2. Individuals are found with serious injuries of unknown origin that are suspicious based on the nature or circumstances of the injury, and on the functional or medical status of the individual.

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		3. Individuals are found with suspicious injuries of unknown origin and have been provided care and supervision by a person who has a confirmed history of abuse. 4. Individuals are subject to punitive techniques in the absence of positive teaching strategies or in the absence of their effectiveness. 5. Individuals suffer death/deterioration due to lack of medical attention and oversight. 6. There is observed abuse and the facility takes no action to correct the situation and protect the individual. §483.420(a)(5) GUIDELINES: The facility is responsible to organize itself in such a manner that it proactively assures individuals are free from serious and immediate threat to their physical and psychological health and safety. Citing of this requirement indicates that there is a high probability that abuse to individuals could occur at any time, or already has occurred and may well occur again, if the individuals are not effectively protected from the serious physical or psychological harm or injury, or if the threat is not removed. A citation of this requirement, therefore, must result in a determination of Condition level non-compliance due to immediate and serious threat. Cross reference W122 for additional guidance. "Threat," as used in this guideline, is any condition/situation which could cause or result in severe, temporary or permanent injury or harm to the mental or physical condition of individuals, or in their death. "Abuse" refers to the ill-treatment, violation, revilement, malignment, exploitation and/or otherwise disregard of an individual, whether purposeful, or due to carelessness, inattentiveness, or omission of the perpetrator. "Physical abuse" refers to any physical motion or action, (e.g., hitting, slapping, punching, kicking, pinching, etc.) by which bodily harm or trauma occurs. It includes use of corporal punishment as well as the use of any restrictive, intrusive procedure to control inappropriate behavior for purposes of punishment. Observe individuals to see if they are bruised, cut, burned (cigarettes, etc.). "Verbal abuse" refers to any use of oral, written or gestured language by which abuse occurs. This includes pejorative and derogatory terms to describe persons with disabilities. "Psychological abuse" includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation, sexual coercion, intimidation, whereby individuals suffer psychological harm or trauma. Individuals must not be subjected to abuse by anyone (including, but not limited to, facility staff, consultants or volunteers, staff of other agencies serving the individual, family members or legal guardians, friends, other individuals, or themselves).

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		Since many individuals residing in ICFs/MR are unable to communicate feelings of fear, humiliation, etc., the assumption must be made that any actions that would usually be viewed as psychologically or verbally abusive by a member of the general public, is also viewed as abusive by the individual residing in the ICF/MR, regardless of that individual's perceived ability to comprehend the nature of the incident. The facility must take whatever action is necessary to protect the individuals residing there. For example, if a facility is forced by court order or arbitration rulings to retain or reinstate an employee believed to be abusive, the facility may need to take other measures (such as assigning the employee to an area where there is no contact with beneficiaries, providing increased supervision and additional training for the employee, appealing the arbitration or court decision or pursuing formal criminal charges) in order to ensure beneficiary safety. SURVEY PROCEDURE: Use the following procedures in the order shown: o Review incident/accident reports or logs for at least a 3-6 month period and for all three shifts. o Review recent hospitalizations or transfers to the facility infirmary as a result of an individual incident or accident. o Note any failure of the facility to provide protective supervision, especially after knowing an individual has in the past been injured as a result of omissions in supervision. (For example, usually after 3 incidents of injury, within a short time-frame, one begins to think about the repetitive nature of the incidents. However, if even one very serious incident resulting in medical intervention has occurred, review it to assure that the facility has taken effective, corrective action.) o After identifying those individuals repeatedly being injured, go to the living unit or wherever the injuries are reoccurring and observe the level of supervision provided. o There are going to be unexplained injuries, given the nature of the population served. However, as a surveyor, you are examining what the facility has done to reduce the probability of further injury. o Observe individuals to determine if there is a pattern of individuals appearing fearful, suspicious, timid, shaking when approached, avoiding eye contact, overly obedient, etc. o Other factors to evaluate include: the needs of the individuals served, the degree of program structure available in the environment, the effectiveness of active treatment strategies, and whether or not the frequency or intensity of injuries is abnormally high or low, etc. These conditions may indicate the potential for a

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		threat which requires indepth investigation and evaluation. §483.420(a)(5) PROBES: Are there patterns of staff conduct which may be punitive, abusive, retributive, counterproductive or a substitute for programming towards self-control? Is there a systematic pattern of incident reports which suggest or allege abuse? How is the facility organized to prevent abuse (i.e., investigative systems, abuse management, analysis of incident and injury patterns, individual/parent/guardian ombudsman systems)? Cross-reference W150 for more probes.
W128	(6) Ensure that clients are free from unnecessary drugs and physical restraints and are provided active treatment to reduce dependency on drugs and physical restraints;	§483.420(a)(6) FACILITY PRACTICES: The use of all drugs and physical restraints is based on individual need and the presenting problem cannot be addressed by other means. An active treatment program which includes mechanisms to reduce dependency on drugs and restraints is in effect, and is based on the needs of the individual. The use of a drug or restraint is discontinued if it is not effective. Drugs are not used at levels which are toxic or otherwise result in deterioration of the individual. §483.420(a)(6) GUIDELINES: The chronic use of restraints may indicate one or more of the following: the individual's developmental and/or behavioral needs are not being met and the appropriateness of placement should be questioned; staff behavior may be prompting behaviors in individuals which result in the chronic use of physical restraints and drugs to control behavior; staff may have inadequate training and/or experience to provide active treatment and employ preventive measures that reduce the levels of behaviors judged to require physical restraints and drugs to control behavior; and restraints may be applied to behaviors which are, in fact, not threatening to the health and welfare of the individual or other individuals and staff. §483.420(a)(6) PROBES: Is there evidence of substitutions of one form of restrictive procedures for another, e.g., as drug usage is reduced, is there widespread increase in the use of time-out and restraint procedures and vice versa? Does the active treatment plan address drug use, physical restraint and/or time-out modification?

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		Are individuals receiving any drugs for which there are no substantiated uses or active monitoring to support their use? How long is use of a psychoactive drug allowed to continue without improvement to the individual? What criteria must be satisified before a psychiatric consultation is requested? Cross reference W295 and W311 for more probes.
W129	(7) Provide each client with the opportunity for personal privacy and	§483.420(a)(7) FACILITY PRACTICES: Individuals have time to be alone, when appropriate, and to have privacy for personal interactions/activities. §483.420(a)(7) GUIDELINES: The facility must have a method of arranging for privacy of visits between individuals with significant relationships, if they do not both reside at the facility. §483.420(a)(7) PROBES: Do individuals actually seek out and utilize opportunities for privacy? Do individuals actually have places to go to be alone and are they allowed to do so? For example, are individuals allowed to go to their room alone? Allowed to go to a quiet private area, or do staff routinely "herd" individuals preventing opportunities for privacy? Are these rights afforded to less-disabled individuals only? Are individuals taught "private area" behavior and responsibilities? What do you see staff do when individuals are not mindful of their or other's privacy? To what extent are individuals talked about in the presence of other individuals?
W130	ensure privacy during treatment and care of personal needs;	§483.420(a)(7) FACILITY PRACTICES: Individuals have privacy during personal hygiene activities (e.g., toileting, bathing, dressing) and during medical/nursing treatments that require exposure of one's body. §483.420(a)(7) GUIDELINES: The facility must examine and treat individuals in a manner that maintains the privacy of their bodies. Only employees directly involved in the treatment are present when treatments are given. Some method or mechanism which ensures privacy (such as a closed door, a drawn curtain or systematically implemented training for an individual to use their own methods) must be employed to shield the individual from passers-by. People not involved in the care of the individual should not be present without their consent while they are being examined or treated. If an individual requires assistance during toileting, bathing, and other personal hygiene activities, staff should assist, giving utmost attention to the individual's

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		need for privacy. There is no prohibition, however, on staff to work with individuals of the opposite sex. Exercise special attention to ensure that your behavior, during onsite observations in the individual's home, does not violate an individual's right to privacy during treatment and care of personal needs. §483.420(a)(7) PROBES: To what extent have accommodations been made so that individuals with physical disabilities, who otherwise would be independent, can perform basic personal hygiene activities without staff present? How does staff preserve personal privacy of individuals when visitors are present?
W131	(8) Ensure that clients are not compelled to perform services for the facility and	§483.420(a)(8) FACILITY PRACTICES: The individual is not required or expected to do chores or work for the facility, other than appropriate care of one's own personal space or shared responsibility for common areas. §483.420(a)(8) GUIDELINES: "Work," as used in the regulation, means any directed activity, or series of related activities which results in benefit to the economy of the facility or in a contribution to its maintenance, or in the production of a salable product. In deciding whether a particular activity constitutes "work" as defined above, the key determinant is if an individual was unavailable to perform the particular activity or function, would the facility be required to hire additional full or part-time staff (or pay overtime to existing staff) in order to properly maintain the facility or to provide necessary care services to individuals, in order to carry out its assigned mission? Individuals are not to be used to provide a source of labor for a facility against their will or in opposition to the objectives of the IPP. Seriously question any situation in which an individual is observed or reported to be "volunteering" to do real work that benefits the facility, or its maintenance without compensation. Interview such individuals to determine if they have given informed consent to such practices and understand that by providing employable services they are able to be compensated. This does not preclude an individual from helping out a friend or being kind to others. Self-care activities related to the care of one's own person are not considered "work" for purposes of compensation. Regular participation in the domiciliary activities of maintaining one's own immediate household or residential living unit which can lead to the individual's greater functional ability to perform independent household tasks is also not considered "work" for the facility. Shared duties are common and appropriate. Included in, but not limited to, these domiciliary tasks are: o Meal planning, food purchasing, food preparation, table setting, serving,
W132	ensure that clients who do work for the facility are compensated for their efforts at prevailing wages and commensurate with their abilities;	

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		dishwashing, etc.; o Household cleaning, laundry; o Clothes repair; o Light yard and house maintenance (painting, simple carpentry, etc.); and o General household shopping, including clothing. In general, participation in any household task which promotes greater independent functioning (and which the individual has not yet learned) is permitted as long as tasks are included in the IPP in written behavioral and measurable terms. This participation must be supervised, and indices of performance should be available. No task may be performed for the convenience of staff (e.g., supervising individuals, running personal errands) or which has no relationship to the individual's IPP. As individuals become widely competent and independent in household tasks, they must not be used in those capacities and represented as "in training" and serious consideration should be given to the individual's potential for even less restrictive residential environments. (See also §483.440(a)(2) and (b)(1).) However, it is acceptable for individuals to engage in household tasks which are in common with other individuals, all sharing the total household tasks commonly shared in nuclear family units. The test in this regard is: o The expectation is that tasks are the general responsibility of the individual, and that the duties rotate to the maximum extent possible; and/or o The individual can assume control in performing the responsibility given (e.g., John has until Thursday at 8 p.m. to clean the living and dining rooms), thereby adding to the development of internal controls and assumption of responsibility by individuals. Work performed by the individual which no other individual is required or expected to do, or is not a regular part of running the household, must be compensated. "Compensated" means the receipt of money or other forms of negotiable compensation for work (including work performed in an occupational training program) which is available to the individual, to be used at his or her discretion in determining the benefits to be derived therefrom. "Prevailing wage" refers to the wage paid to non-disabled workers in nearby industry or the surrounding community for essentially the same type, quality and quantity of work or work requiring comparable skills. A working individual must be paid at least the prevailing minimum wage except when an appropriate certificate has been obtained by the facility in accordance with current regulations and guidelines issued under the Fair Labor Standards Act, as amended. Any individual performing work, as defined above, must be compensated in direct proportion to his or her productivity as measured in work equivalents of a regular

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		employee's output. For example, if an individual's productivity for a particular work activity or function is determined to be 30% of normal output for an average non-disabled worker, and the prevailing wage is $4.00 an hour, then the individual should be compensated in money at a rate of one dollar and twenty cents per hour (.30 x $4.00 = $1.20). If a piece rate can be determined for a particular job, an individual is paid based on the number of pieces he or she produces. An individual's pay is not dependent on the production of other individuals when he or she works in a group. When the individual's active treatment program includes assignment to occupational or vocational training or work, specific work objectives of anticipated progress should be included in the IPP along with reasons for the assignments. If the training of individuals on particular occupational activities or functions involves "real work" to be accomplished for the facility, the individuals must be compensated based on ability. For example, if in the process of work training activities involved with learning to clean a floor, the floor for a particular building is cleaned and does not require further janitorial cleanup, then the individual must be compensated for this activity. §483.420(a)(8) PROBES: Are individuals assigned to bathe, toilet or feed other individuals? Is each individual who provides work for the facility allowed to refuse to work for the facility? Are there individual payment records? If an individual makes less than the prevailing wage, can that person's individual production or performance record be retrieved? If time studies were conducted, did the facility measure the same skills as performed by persons who are not disabled? Are household tasks assigned and changed equitably? Do individuals have reasonable responsibilities, to the extent possible, for keeping their own private areas of living unit clean and neat? Are individuals coerced to work for staff in order to gain privileges? Are individuals trained to perform services for the facility for reinforcers or tokens rather than pay? Do individuals work the same job everyday without pay?
W133	(9) Ensure clients the opportunity to communicate, associate and meet privately with individuals of their choice,	§483.420(a)(9) GUIDELINES: Space must be provided for individuals to receive visitors in reasonable comfort and privacy.

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		§483.420(a)(9) PROBES: Does the facility provide individuals with the opportunity to form individual relationships with others including opportunities to experience personal relationships both within and outside the facility? What pattern of freedom of movement do you see at the facility? Do most individuals move freely? Few? On what basis is freedom of movement restricted? Is this dealt with programmatically in the individual program plan for each individual? How often is this restriction re-evaluated?
W134	and to send and receive unopened mail;	§483.420(a)(9) GUIDELINES: Assistance must be provided to individuals who require help in reading or sending mail. Refer to W145. §483.420(a)(9) PROBES: How do individuals send and receive mail? Do staff assist individuals who are unable to open and read mail themselves? Is writing assistance provided?
W135	(10) Ensure that clients have access to telephones with privacy for incoming and outgoing local and long distance calls except as contraindicated by factors identified within their individual program plans;	
W136	(11) Ensure clients the opportunity to participate in social, religious, and community group activities;	§483.420(a)(11) FACILITY PRACTICES: Individuals are involved in various types of activities in the community (e.g., going to parks, movies, restaurants, church, community meetings and events) based on their interests and choices. Individuals are taught the skills and are provided with appropriate levels of support, commensurate with functional levels, for community participation. §483.420(a)(11) GUIDELINES: Outdoor and out of home activities are planned for all individuals on a regular basis. §483.420(a)(11) PROBES: Are all activities agency-centered or sponsored? Are religious preferences known and honored?

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		What is the level of individual participation (relevant to level of individual functioning): o Fully independent? o Staff assisted/individual participation? o Total staff assistance? Are the individuals allowed to participate independently in activities commensurate with their level of functioning and interest? What is the facility's system to facilitate an individual's participation? What does the facility do to draw out non-participating individuals to the point that the individual makes his/her own active choice to participate or not? Does the facility arrange for individuals to participate in community integrated activities individually or in small groups (3 or less) at least part of the time? Does the facility arrange age and interest appropriate outside activities for individuals with the community (e.g., recreation centers, churches, social clubs)?
W137	(12) Ensure that clients have the right to retain and use appropriate personal possessions and clothing, and	§483.420(a)(12) FACILITY PRACTICES: Individuals have personal possessions and clothing which meet their needs, interests and choices. Individuals have free access to their own possessions and clothing. Individuals, who are unable to access and use personal possessions and clothing appropriately, are involved in programs to learn the necessary skills to do so. §483.420(a)(12) GUIDELINES: All individual possessions regardless of their apparent value to others must be treated with respect, for what they are and for what they may represent to the individual. The facility should encourage individuals to use or display possessions of his or her choice in a culturally normative manner. Appropriate personal possessions includes personal care and hygiene items. Individuals should not be without personal possessions because of the behavior of others with whom they live. If a method for identifying personal effects is used, it should be inconspicuous and in a manner that will assist the individual to identify them. "Appropriate" clothing means a supply of clothing that is sufficient, in good repair, accounts for a variety of occasions and seasons, and appropriate to age, size, gender, and level of activity. Modification or adaptation of clothing fasteners should be considered based on the needs of an individual with a physical disability to be independent. As appropriate, each individual's active treatment program maximizes opportunities for choice and self-direction with regard to choosing and shopping for clothing which

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		enhances his or her appearance, and selecting daily clothing in accordance with age, sex and cultural norms. Individuals are permitted to keep personal clothing and possessions for their use while in the facility. Determine how the facility both ensures the safety of personal possessions while at the same time providing individual access to them when the individual chooses. Individuals are provided the opportunity, encouraged, and trained to use age-appropriate materials. The term "age-appropriate" refers to anything that reinforces recognition of the individual as a person of a certain chronological age. The facility's environment must be furnished with materials and activities that will enhance opportunities for growth. Determine whether the failure of an individual to achieve functional, adaptive skills, or to have opportunities to make informed choices, or to achieve any positive outcomes is a result of the constant use of materials or participation in activities that are age-inappropriate. §483.420(a)(12) PROBES: Are individuals dressed in their own clean, neat and attractive clothing? Is it of the correct size and in good condition? Is clothing appropriate for the weather and type of activity? To what extent is there a pattern of slacks that are too long or too short? Are cords and pins used to keep pants up instead of belts? To what extent does the facility provide items of lesser quality or provide only one type of a particular item? Is there clothing for a variety of activities (e.g., clothing for church, casual social functions, sport events)? Do colors, styles, and designs match and conform with community standards? Are individuals assisted in clothes selection, room decoration and other forms of self-expression? Are individuals satisfied with the access to and choice of the kinds and numbers of personal possessions they have? How frequently during the course of the day do you observe individuals using their personal possessions? Are individuals' personal decorative possessions displayed? Are individual possessions protected?

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		To what extent is there a pattern of individual loss, due to theft or destruction by others? What does the facility do to prevent loss? Is it successful?
W138	ensure that each client is dressed in his or her own clothing each day; and	§483.420(a)(12) PROBES: To what extent are items of clothing such as pajamas, underwear, and socks, considered "stock" items as opposed to belonging to individuals?
W139	(13) Permit a husband and wife who both reside in the facility to share a room.	
	(b) Standard: Client finances.	
	(1) The facility must establish and maintain a system that--	
W140	(i) Assures a full and complete accounting of clients' personal funds entrusted to the facility on behalf of clients; and	§483.420(b)(1)(i) GUIDELINES: A "full and complete accounting for personal funds" does not need to document accounting for incidental expenses or "pocket money," funds a capable individual handles without assistance, funds dispensed to an individual under a program to train the individual in money management, and funds that are not entrusted to the facility (e.g., funds paid directly to the individual's representative payee).
W141	(ii) Precludes any commingling of client funds with facility funds or with the funds of any person other than another client.	§483.420(b)(1)(ii) GUIDELINES: Although prudent to do so, there is no Federal requirement to maintain individuals' personal funds in financial institutions in interest bearing accounts, or in accounts separate from other individual accounts. However, if the facility elects to pool individuals' funds in an interest bearing account, including common trust accounts, it is expected to know the interest separately accrued by each individual, as part of its required accounting of funds. Interest accumulated to an individual's account belongs to the individual, not the facility.
W142	(2) The client's financial record must be available on request to the client, parents (if the client is a minor) or legal guardian.	§483.420(b)(2) GUIDELINES: Parents or other family members should not have automatic access to the financial records of adult individuals. It is not necessary that a facility be required to furnish an annual financial statement to the individual or the individual's family, since the facility is already required to make the financial record available at any time upon request. The individual, in turn, is free to choose to make his or her financial record available to anyone else.
	(c) Standard: Communication with clients, parents, and guardians.	
	The facility must- -	

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W143	(1) Promote participation of parents (if the client is a minor) and legal guardians in the process of providing active treatment to a client unless their participation is unobtainable or inappropriate;	§483.420(c)(1) GUIDELINES: "Unobtainable," as used in this standard, means that the facility has made a bonafide effort to seek parental or guardian participation in the process, even though the effort may ultimately be unsuccessful (for example, the parent may be impossible to locate or may prove unwilling or unable to participate). "Inappropriate" as used in this standard means that the parent or legal guardian's behavior is so disruptive or uncooperative that others cannot effectively participate; the individual does not wish his or her parent to participate, and the individual is competent to make this decision; or there is strong evidence that the parent or guardian is not acting on the individual's behalf or in the individual's best interest. In the case of the latter, determine what the facility has done to bring effective resolution to the problem. §483.420(c)(1) PROBES: Are families contacted for involvement in planning services/treatments for individuals? On a routine basis, what kinds of activities, information, and problems get communicated? How does the facility develop and maintain active family/guardian participation? Does the facility respond to the wishes of non-adjudicated adult individuals who do not wish their family's involvement? Does information in the individual record correlate with information provided families? Are parents and guardians allowed to talk to direct care and service providers? What is the facility's basis for denying participation by the parents or guardians? Is there a pattern to the denials or to the reasons stated? How does the facility explain the meaning of "active treatment" to parents and guardians? To what extent are families informed of how to reinforce training and/or the maintenance of skills while individuals are with them? What efforts has the facility made to accommodate scheduling problems for interdisciplinary team or other meetings of families?
W144	(2) Answer communications from clients' families and friends promptly and appropriately;	§483.420(c)(2) GUIDELINES: Where possible, randomly select a family or guardian to validate the quality, nature and frequency of the communications between the facility and families or guardians (but only with their consent). There is no requirement that each contact with family and

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		friends be documented. §483.420(c)(2) PROBES: How does the facility communicate with families and friends of those served? Is there a pattern of lag time between contact and response which suggest responses are not timely?
W145	(3) Promote visits by individuals with a relationship to the client (such as family, close friends, legal guardians and advocates) at any reasonable hour, without prior notice, consistent with the right of that client's and other clients' privacy, unless the interdisciplinary team determines that the visit would not be appropriate;	§483.420(c)(3) GUIDELINES: Any limitations of visitors are recorded by the interdisciplinary team with reason and time limits given. Decisions to restrict a visitor must be reviewed and re-evaluated each time the IPP is reviewed or at the individual's request. If you find broad restrictions, review general facility access policies. The facility should have arrangements available to provide privacy for families and others when visiting with individuals. §483.420(c)(3) PROBES: Is there a systematic pattern of unreasonable restrictions on visitors in terms of when they can come, where they can go on the facility's property and to whom they can speak?
W146	(4) Promote visits by parents or guardians to any area of the facility that provides direct client care services to the client, consistent with the right of that client's and other clients' privacy;	§483.420(c)(4) PROBES: Is there a pattern to the types of restricted locations? Is there evidence such as "no admittance" signs or policies against visitors in any of these areas?
W147	(5) Promote frequent and informal leaves from the facility for visits, trips, or vacations; and	§483.420(c)(5) GUIDELINES: It is not acceptable for a facility to sponsor or allow individuals to take a particular type of trip that is contraindicated. For example, in the situation of an individual subject to abuse by a parent, the facility obviously is not required to permit such a trip. However, as with any right that may need to be modified or limited, the individual should be provided with the least restrictive and most appropriate alternative available. §483.420(c)(5) PROBES: What is the frequency of these outings? What types of outings? Are outings age-appropriate? How does the facility provide choice in outings? Can individuals choose not to participate?

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W148	(6) Notify promptly the client's parents or guardian of any significant incidents, or changes in the client's condition including, but not limited to, serious illness, accident, death, abuse, or unauthorized absence.	§483.420(c)(6) GUIDELINES: "Significant" incidents or changes in the individual's condition refers to any type of occurrence or event, that is perceived to have some level of importance to the individual, family or guardian. Examples include, but are not limited to, allegations of mistreatment, psychological trauma experienced by the individual, loss or change of a program service or staff person, entry or placement in new programs or agencies, day-to-day events on which family members express interest to be informed, etc. §483.420(c)(6) PROBES: Are family members/guardians informed of incidents/alleged abuse? Are telephone numbers and addresses for parents and guardians kept and periodically updated? What is the time frame for notification?
	(d) Standard: Staff treatment of clients.	
W149	(1) The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect or abuse of the client.	§483.420(d)(1) FACILITY PRACTICES: The facility, through implementation of its policies, has set up a structure which protects individuals from mistreatment, neglect and abuse. §483.420(d)(1) GUIDELINES: "Mistreatment" as used in this standard, includes behavior or facility practices that result in any type of individual exploitation such as financial, sexual, or criminal. "Neglect" means failure to provide goods or services necessary to avoid physical or psychological harm. See W127 for definitions related to "abuse." §483.420(d)(1) PROBES: Refer to W186 because there is often a relationship between the adequacy of facility staffing and staff treatment of individuals. Is there a pattern among incidents of alleged abuse, accidents, behavior programs, psychoactive drug use, staff training, and adequacy of staffing levels that may suggest possible mistreatment, neglect or abuse of individuals? How does the facility monitor staff treatment of individuals to ensure that the requirements are not being violated?
W150	(i) Staff of the facility must not use physical, verbal, sexual or psychological abuse or punishment.	§483.420(d)(1)(i) GUIDELINES: See W127, Facility Practices, as related specifically to staff of the facility.

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		A citation of this requirement indicates that abuse to an individual by staff of the facility is highly likely to occur or has already occurred and may well occur again if the individual is not effectively protected. A citation of this requirement, therefore, must result in Condition-level non-compliance due to immediate and serious threat. Cross reference W122 and W127. §483.420(d)(1)(i) PROBES: Can staff define what constitutes abuse and punishment? Are programs or policies "masks" for punitive, abusive controls? How does the facility actively promote respect for individuals? How do staff members set acceptable behavioral limits for individuals? Does group punishment occur? Does demeaning, belittling or degrading punishment occur? Do staff speak loudly, harshly? In negative, punishing terms? With threats, coercion? Cross-reference W127 for definitions and additional probes.
W151	(ii) Staff must not punish a client by withholding food or hydration that contributes to a nutritionally adequate diet.	§483.420(d)(1)(ii) GUIDELINES: Cross-reference W465.
W152	(iii) The facility must prohibit the employment of individuals with a conviction or prior employment history of child or client abuse, neglect or mistreatment.	§483.420(d)(1)(iii) FACILITY PRACTICES: No one hired after October 3, 1988, has had a conviction or a prior employment history of child or client abuse, neglect or mistreatment of which the facility was aware based on pre-employment screening. No one with a conviction or substantiated allegation of child or client abuse, neglect or mistreatment occurring outside the jurisdiction of the ICF/MR after October 3, 1988, regardless of employment date, is employed by the facility. §483.420(d)(1)(iii) GUIDELINES: This regulation applies to the hiring of new employees on or after 10/3/88. The facility is required to screen potential employees for a prior employment history of child or client abuse, neglect or mistreatment, as well as for any conviction based on those offenses. The abuse, neglect or mistreatment must be directed toward a child or an individual who is a client (resident, patient) in order for the prohibition of employment to apply.

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		This requirement also applies to acts of abuse, neglect or mistreatment committed by a current ICF/MR employee outside the jurisdiction of the ICF/MR (e.g., in the community or in another health care facility). A substantiated allegation of abuse, neglect or mistreatment which occurred after October 3, 1988 (regardless of the date of the person's employment in the ICF/MR), and which resulted in the termination of that person's employment from another health care facility, becomes a part of the person's employment history and the ICF/MR is prohibited from continuing to employ the individual. For example, an individual who abused a resident in a nursing facility and as a result, is barred from employment in the nursing home setting would also be prohibited from employment in the ICF/MR. While facilities are not required to periodically screen existing employees, if the facility becomes aware that such action has been taken against an employee, the facility is required to prohibit continued employment. This is also true of any conviction in a court of law for child or client (resident, patient) abuse, neglect or mistreatment. Therefore, conviction for abusing one's own child is also a reason employment would be prohibited. The definition of "mistreatment" under the guideline at W153 includes financial exploitation. Therefore, if an employee was convicted or had a prior employment history of theft of an individual's funds, that would also be a reason employment would be prohibited. Access other information, as appropriate, including information contained in "closed" records, in order to adequately evaluate compliance. §483.420(d)(1)(iii) PROBES: How does the facility screen employees for previous convictions? Who are the facility's new hires? Has the facility implemented its system in such a fashion to ensure that W152 has been achieved?
W153	(2) The facility must ensure that all allegations of mistreatment, neglect or abuse, as well as injuries of unknown source, are reported immediately to the administrator or to other officials in accordance with State law through established procedures.	§483.420(d)(2) GUIDELINES: The facility is responsible for reporting any injuries of unknown origin and any allegations of mistreatment to an individual residing in the facility regardless of who is the perpetrator (e.g., facility staff, parents, legal guardians, volunteer staff from outside agencies serving the individual, neighbors, or other individuals, etc.). §483.420(d)(2) PROBES: How many alleged violations have been reported this year? Last year? What mechanisms are in place to ensure prompt detection, reporting, and appropriate follow-up?
W154	(3) The facility must have evidence that all alleged	§483.420(d)(3) GUIDELINES: The facility is responsible for investigating all injuries of unknown origin and

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	violations are thoroughly investigated and	allegations of mistreatment, neglect or abuse. The particular mechanisms developed by a facility for investigation are at its discretion, provided that alleged violations of individual rights are thoroughly investigated and appropriate actions are taken. Review reports of investigations to determine that necessary information relevant to the incident was obtained and considered. §483.420(d)(3) PROBES: After you review reports of investigation, do you identify a pattern to the depth, thoroughness, conclusions and actions taken that suggest: o Comprehensive and responsive investigations? o Well conducted but negated or altered reports? o Shallow or routinized investigations?
W155	must prevent further potential abuse while the investigation is in progress.	
W156	(4) The results of all investigations must be reported to the administrator or designated representative or to other officials in accordance with State law within five working days of the incident and,	§483.420((d)(4) GUIDELINES: Some States require that allegations of abuse must be reported to the police. HCFA cannot regulate the activities of the police. However, if the police take longer than five working days for their investigation, the facility is still required to complete an internal investigation report of findings within the five day timeframe. "Working days" means Monday through Friday, excluding State and Federal holidays. §483.420(d)(4) PROBES: If a report of known or suspected abuse or neglect involves the acts or omissions of the administrator, how has the provider arranged for an unbiased review of the allegation (such as, an authority outside of the facility investigating the report and, if necessary, taking appropriate corrective action)?
W157	if the alleged violation is verified, appropriate corrective action must be taken.	§483.420(d)(4) FACILITY PRACTICES: The seriousness of the violation is considered by the facility to determine appropriate corrective action. When the intentional action or inaction of a staff person has resulted in abuse, neglect or mistreatment which was a serious and immediate threat to the individual's health and safety, the staff person's employment is terminated. The corrective action taken by the facility is reasonably likely to assure that the abuse, neglect, mistreatment or injury will not occur again. §483.420(d)(4) GUIDELINES: This requirement refers to corrective action taken based upon findings of investigations of incidents which have occurred within the jurisdiction of the facility. It requires that the seriousness of infractions be weighed in the determination of what action is necessary by the facility to correct the situation appropriately. In cases of abuse, neglect or mistreatment by staff, where extenuating circumstances exist and dependent on the nature of the infraction, a remedy that is consistent with appropriate progressive disciplinary measures may be acceptable. When the intentional action or inaction of a staff person has resulted in abuse, neglect or

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		mistreatment which poses a serious and immediate threat to individuals' health and safety, termination of employment is the only acceptable corrective action. Appropriate corrective action is also required for findings of abuse, neglect or mistreatment by other individuals residing in the facility, staff of outside agencies, parents or any other person, and for injuries to individuals resulting from controllable environmental factors. Appropriate corrective action is defined as that action which is reasonably likely to prevent the abuse, neglect, mistreatment or injury from recurring. When an employee appeals a finding of abuse by the facility, whether through arbitration or in a court of law, the decision of the arbitrator or the court of law is then considered the final finding. If the arbitrator found that the charges lacked substance, the allegation would be considered unsubstantiated. The facility, however, is still required to ensure that individuals residing in the facility are not subjected to physical, verbal, sexual or psychological abuse or punishment by W127. An arbitrator may find that the allegation of abuse is substantiated, but impose a lesser penalty than that which was sought by the facility. For example, the facility may seek termination of employment as the appropriate corrective action but the arbitrator determines that a 10 day suspension is more appropriate. The facts of the situation will have to be evaluated by the surveyor and a judgement made regarding appropriateness. Therefore, while the facility is permitted by the regulation to exercise judgement regarding appropriate corrective action, the surveyor must also exercise judgement and may determine that the corrective action is NOT reasonably likely to prevent the abuse from recurring. §483.420(d)(4) PROBES: After investigations have been completed, how many alleged violations culminated in progressive discipline actions? Staff discharges? As a result of the facility's investigations, is there a pattern of reduction of allegations?

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W158	§483.430 Condition of participation: Facility staffing.	§483.430 COMPLIANCE PRINCIPLES: The Condition of Participation of Facility Staffing is met when: o The Condition of Participation of Active Treatment is met (i.e., there are sufficient numbers of competent, trained staff to provide active treatment.); and o The Condition of Participation of Client Protections is met (i.e., there are sufficient numbers of competent, trained staff to protect individuals' health and safety.). The Condition of Participation of Facility Staffing is not met when: o The Condition of Participation of Active Treatment has first been determined to be not met and the lack of active treatment has resulted from insufficient numbers of staff or lack of trained, knowledgeable staff to design and carry out individual's programs; or o The Condition of Participation of Client Protections has first been determined to be not met and the lack of client protection has resulted from insufficient numbers of competent, trained staff to protect the health and safety of individuals.
	(a) Standard: Qualified mental retardation professional.	
W159	Each client's active treatment program must be integrated, coordinated and monitored by a qualified mental retardation professional	§483.430(a) FACILITY PRACTICES: There is an assigned qualified mental retardation professional (QMRP). There are sufficient numbers of QMRPs to accomplish the job. The QMRP observes individuals, reviews data and progress, and revises programs based on individual need and performance. The QMRP ensures consistency among external and internal programs and disciplines. The QMRP ensures service design and delivery which provides each individual with an appropriate active treatment program. The QMRP ensures that any discrepancies or conflicts between programmatic, medical, dietary, and vocational aspects of the individual's assessment and program are resolved. The QMRP ensures a follow-up to recommendations for services, equipment or programs. The QMRP ensures that adequate environmental supports and assistive devices are present to promote independence. §483.430(a) GUIDELINES: View the person serving in the QMRP role as pivotal to the adequacy of the program the

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		individual receives, since it is this role that is intended to ensure that the individual receives those services and interventions necessary by competent persons capable of delivering them. The paramount importance of having persons competent to judge and supervise active treatment issues cannot be overstated. An individual's IPP may be coordinated and monitored by more than one QMRP or by other staff persons who perform the QMRP duties. There must, however, be one QMRP who is assigned primary responsibility and accountability for the individual's IPP and the QMRP function. The regulations do not specify if the person designated as QMRP must do the duties of a QMRP exclusively, or is allowed to perform other professional staff duties in addition. The facility has the flexibility to allocate staff resources in whatever manner it believes is necessary as long as it ensures that the QMRP function is performed effectively for each individual. The test of whether the number of QMRPs is adequate rests with the ability of the facility to provide the services described in §483.430(a) in an effective manner. The number will vary depending on such factors as the number of individuals the facility serves, the complexity of needs manifested by these individuals, the number, qualifications and competencies of additional professional staff members, and whether or not other duties are assigned to the QMRP function. §483.430(a) PROBES: Are the QMRP functions actually being carried out, or is paperwork simply reviewed? Are timely modifications of unsuccessful programs or development of programs for unaddressed, but significant needs made or ensured by the QMRP function? Are program areas visited and are performance and problems of individuals discussed? Does the plan flow from only the original diagnosis/assessment? Does it take into consideration interim progress on plans and activities? Does the QMRP make recommendations and requests on behalf of individuals? How does the facility respond?
	who--	
W160	(1) Has at least one year of experience working directly with persons with mental retardation or other developmental disabilities; and	§483.430(a)(1) GUIDELINES: "Experience" means providing professional services, either paid or volunteer, in a setting that serves persons with mental retardation. The experience working directly with persons with mental retardation or other developmental disabilities can be obtained prior to or after obtaining the qualifying degree or credentials. Experience as a State or Federal surveyor of ICFs/MR does NOT qualify an individual as a QMRP.

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	(2) Is one of the following:	
W161	(i) A doctor of medicine osteopathy.	
W162	(ii) A registered nurse.	
W163	(iii) An individual who holds at least a bachelor's degree in a professional category specified in paragraph (b)(5) of this section.	
	(b) Standard: Professional program services.	
W164	(1) Each client must receive the professional program services needed to implement the active treatment program defined by each client's individual program plan.	§483.430(b)(1) FACILITY PRACTICES: Individuals receive professional services when the comprehensive functional assessment or the active treatment program defined by the IPP requires the knowledge, skills and expertise of someone specially trained in a given discipline in order to be effectively implemented. In the presence of a functional deficit, there is input by the relevant professional discipline(s) in order to assess the individual and develop a relevant active treatment program. §483.430(b)(1) GUIDELINES: For an active treatment program to be responsive to the individual's unique needs, there must be a foundation of competent professional knowledge that can be drawn upon in the implementation of the interdisciplinary team process. Individuals with developmental deficits will require initial, temporary, or ongoing services from professional staff, knowledgeable about contemporary care practices associated with these areas. A special mention needs to be made that individuals should not be provided with services that are not needed (e.g., if an individual is basically healthy and not on medication, then the individual should not be provided extensive health and health-related services). The needs identified in the initial comprehensive functional assessment, as required in §483.440(c)(3)(v), should guide the team in deciding if a particular professional's further involvement is necessary and, if so, to what extent professional involvement must continue on a direct or indirect basis. Since such needed professional expertise may fall within the purview of multiple professional disciplines, based on overlapping training and experience, determine if the facility's delivery of professional services is adequate by the extent to which individuals' needs are aggressively and competently addressed. Some examples in which professional expertise may overlap include:

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		o Physical development and health - nurse (routine medical or nursing care needs that do not interfere with participation in other programs); physician, physician assistant, nurse practitioner (acute major medical intervention, or the treatment of chronic medical needs which will be dependent upon an individual's success or failure in other treatment programs). o Nutritional status - nurse (routine nutritional needs that do not affect participation in other programs); nutritionist or dietitian (chronic health problems related to nutritional deficiencies, modified or special diets). o Sensorimotor development: physical educators, adaptive physical educators, recreation therapists, (routine motor needs involving varying degrees of physical fitness or dexterity); special educators or other visual impairment specialists (specialized mobility training and orientation needs); occupational therapist, physical therapist, physiatrist (specialized fine and gross motor needs caused by muscular, neuromuscular, or physical limitations, and which may require the therapeutic use of adaptive equipment or adapted augmentative communication devices to increase functional independence); dietitians to increase specialized fine and gross motor skills in eating. o Affective (emotional) development: special educators, social workers, psychologists, psychiatrists, mental health counselors, rehabilitation counselors, behavior therapists, behavior management specialists. o Speech and language (communication) development: speech-language pathologists, special educators for people who are deaf or hearing impaired. o Auditory functioning: audiologists (basic or comprehensive audiologic assessment and use of amplification equipment); speech-language pathologists (like audiologists, may perform aural rehabilitation); special educators for individuals who are hearing impaired. o Cognitive development: teacher (if required by law, i.e., school aged children, or if pursuit of GED is indicated), psychologist, speech-language pathologist. o Vocational development: vocational educators, occupational educators, occupational therapists, vocational rehabilitation counselors, or other work specialists (if development of specific vocational skills or work placement is indicated). o Social Development: teachers, professional recreation staff, social workers, psychologists (specialized training needs for social skill development). o Adaptive behaviors or independent living skills. Special educators, occupational therapists.
	Professional program staff must work	
W165	directly with clients	§483.430(b)(1) FACILITY PRACTICES: Individuals receive interventions or services directly from professional staff when required by individual needs, program design, implementation, or monitoring.
W166	and with paraprofessional, nonprofessional and other professional program staff who work with clients.	§483.430(b)(1) FACILITY PRACTICES: When required by individual need, program design, implementation, or monitoring, professional staff work directly with paraprofessional, nonprofessional and other professional program staff to assure that these individuals have the skills

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		necessary to carry out the needed interventions. §483.430(b)(1) GUIDELINES: There are some individuals in ICFs/MR who can often have their needs effectively met without having direct contact with professional staff on a daily basis. The intent of the requirement is not to require that professionals work directly with individuals on a daily basis, but only as often as an individual's needs indicate that professional contact is necessary. The amount and degree of direct care that professionals must provide will depend on the needs of the individual and the ability of other staff to train and direct individuals on a day-to-day basis.
W167	(2) The facility must have available enough qualified professional staff to carry out and monitor the various professional interventions in accordance with the stated goals and objectives of every individual program plan.	§483.430(b)(2) FACILITY PRACTICES: Each individual receives professional interventions as needed and specified in the IPP, in sufficient quantity to assure correct implementation. §483.430(b)(2) GUIDELINES: If there is sufficient evidence that para- and non-professional staff demonstrate the needed competencies to carry through with intervention strategies, you may be satisfied there is sufficient professional staff to carry out the active treatment program. However, if the professional's expertise is not demonstrable at the para- and non-professional staff level, question both the numbers of professional staff and the effectiveness of the transdisciplinary training of para- and non-professional staff. §483.430(b)(2) PROBES: Are these services available when they are most beneficial for the individual? Are these people available to staff on other shifts? Weekend staff? Are professional staff available to monitor the implementation of individual programs if necessary?
W168	(3) Professional program staff must participate as members of the interdisciplinary team in relevant aspects of the active treatment process.	§483.430(b)(3) FACILITY PRACTICES: When necessary to develop, implement or monitor an individual's active treatment program, appropriate professional staff participate as interdisciplinary team (IDT) members. §483.430(b)(3) GUIDELINES: "Participate" means providing input through whatever means is necessary to ensure that the individual's IPP is responsive to the individual's needs. The purpose of the interdisciplinary team process is to provide team members with the opportunity to review and discuss information and recommendations relevant to the individual's needs, and to reach decisions as a team, rather than individually, on how best to address those needs. Therefore, determine whether or not there is a pattern of active treatment based on professional participation in the process. Without a negative outcome to demonstrate that professional involvement in any aspect7

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		of the active treatment process (e.g., comprehensive functional assessment, IPP development, program implementation, etc.) was insufficient or inaccurate, the facility is allowed the flexibility to use its resources in a manner that works in behalf of the client, in accordance with the regulations.
W169	(4) Professional program staff must participate in on-going staff development and training in both formal and informal settings with other professional, paraprofessional, and nonprofessional staff members.	§483.430(b)(4) FACILITY PRACTICES: Professional staff receive training in their own discipline to assure adequate delivery of services and to be aware of developments in their field. Professional staff receive training in other disciplines to the extent necessary to meet the needs of each individual. Professional staff provide training to others. §483.430(b)(4) GUIDELINES: "Participate" means both seeking out self-training and provision of training to others.
W170	(5) Professional program staff must be licensed, certified, or registered, as applicable, to provide professional services by the State in which he or she practices.	§483.430(b)(5) PROBES: How does the facility verify that its professionals meet State licensing requirements?
	Those professional program staff who do not fall under the jurisdiction of State licensure, certification, or registration requirements, specified in §483.410(b), must meet the following qualifications:	
W171	(i) To be designated as an occupational therapist, an individual must be eligible for certification as an occupational therapist by the American Occupational Therapy Association or another comparable body.	§483.430(b)(5)(i)-(ix) GUIDELINES: The introductory phrase "to be designated as- - -" means that a provider is allowed to represent him or herself as a professional provider in that discipline, only if the provider meets State licensing requirements, or if the particular discipline does not fall under State licensure requirements, the provider meets the qualifications specified in §§483.430(b)(5)(i)-(ix). A person who is not qualified, for example, as a social worker, may not be referred to as a social worker per se. Nevertheless, such a person may be able to provide social services in an ICF/MR if there is no conflict with State law, and as long as the individuals' needs are met.

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W172	(ii) To be designated as an occupational therapy assistant, an individual must be eligible forcertification as a certified occupational therapy assistant by the American Occupational Therapy Association or another comparable body.	
W173	(iii) To be designated as a physical therapist, an individual must be eligible for certification as a physical therapist by the American Physical Therapy Association or another comparable body.	
W174	(iv) To be designated as a physical therapy assistant, an individual must be eligible for registration by the American Physical Therapy Association or be a graduate of a two year college-level program approved by the American Physical Therapy Association or another comparable body.	
W175	(v) To be designated as a psychologist, an individual must have at least a master's degree in psychology from an accredited school.	
	(vi) To be designated as a social worker, an individual must- -	

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W176	(A) Hold a graduate degree from a school of social work accredited or approved by the Council on Social Work Education or another comparable body; or (B) Hold a Bachelor of Social Work degree from a college or university accredited or approved by the Council on Social Work Education or another comparable body.	
	(vii) To be designated as a speech-language pathologist or audiologist, an individual must- -	
W177	(A) Be eligible for a Certificate of Clinical Competence in Speech-Language Pathology or Audiology granted by the American Speech-Language-Hearing Association or another comparable body; or (B) Meet the educational requirements for certification and be in the process of accumulating the supervised experience required for certification.	
W178	(viii) To be designated as a professional recreation staff member an individual must have a bachelor's degree in recreation or in a specialty area such as art, dance, music or physical education.	
W179	(ix) To be designated as a professional dietitian, an individual must be eligible for registration by the American Dietetics Association.	§483.430(b)(5)(ix) GUIDELINES: The Commission on Dietetic Accreditation of the American Dietetic Association is the organization to whom the American Dietetic Association delegates this responsibility.

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W180	(x) To be designated as a human services professional an individual must have at least a bachelor's degree in a human services field (including, but not limited to: sociology, special education, rehabilitation counseling, and psychology).	§483.430(b)(5)(x) GUIDELINES: The intent for including a "human services professional" category is to expand the number and types of persons who could qualify as QMRPs, while still maintaining acceptable professional standards. "Human services field" includes all the professional disciplines stipulated in §§483.430(a)(3)(i)(ii) and §§483.430(b)(5)(i)-(ix), as well as any related academic disciplines associated with the study of: human behavior (e.g., psychology, sociology, speech communication, gerontology etc.), human skill development (e.g., education, counseling, human development), humans and their cultural behavior (e.g., anthropology), or any other study of services related to basic human care needs (e.g., rehabilitation counseling), or the human condition (e.g., literature, the arts). An individual with a "bachelors degree in a human services field" means an individual who has received: at least a bachelor's degree from a college or university (master and doctorate degrees are also acceptable) and has received academic credit for a major or minor coursework concentration in a human services field, as defined above. Although a variety of degrees may satisfy the requirements, majors such as geology and chemical engineering are not acceptable. Taking into consideration a facility's needs, the types of training and coursework that a person has completed, and the intent of the regulation, the facility and you can exercise wide latitude of judgment to determine what constitutes an acceptable "human services" professional. Again, the key concern is the demonstrated competency to do the job.
W181	(xi) If the client's individual program plan is being successfully implemented by facility staff, professional program staff meeting the qualifications of paragraph (b)(5)(i) through (x) of this section are not required- - (A) Except for qualified mental retardation professionals; (B) Except for the requirements of paragraph (b)(2) of this section concerning the facility's provision of enough qualified professional program staff; and (C) Unless otherwise specified by State licensure and certification requirements.	

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	(c) Standard: Facility staffing.	
W182	(1) The facility must not depend upon clients or volunteers to perform direct care services for the facility.	§483.430(c)(1) FACILITY PRACTICES: The facility has sufficient staff to provide needed care and services without the use of volunteers or enlisting the help of individuals residing in the facility. §483.430(c)(1) GUIDELINES: Volunteers may provide supplementary services. The facility may not rely on volunteers to fill required staff positions and perform direct care services. Examine closely the adequacy of staffing when individuals served are engaged in the care, training, treatment or supervision of other individuals, either as part of training, "volunteer work," or normal daily routines. (See W131-W132 for additional interpretation of productive work done as a "volunteer" or as part of the individual's active treatment program.) The test of adequacy is whether or not there is sufficient staff to accomplish the job in the absence of the individual's work. Work done as part of an active treatment training program requires that the staff are monitoring and teaching new skills as part of the IPP. §483.430(c)(1) PROBES: After observing client or volunteer activities done with individuals served, can you determine whether or not those same services should and could have been provided reasonably by the facility, in the absence of those clients or volunteers? Are individuals served assigned to bathe, toilet, feed or supervise other individuals served in the absence of hired staff?
W183	(2) There must be responsible direct care staff on duty and awake on a 24-hour basis, when clients are present, to take prompt, appropriate action in case of injury, illness, fire or other emergency, in each defined residential living unit housing- - (i) Clients for whom a physician has ordered a medical care plan; (ii) Clients who are aggressive, assaultive or security risks; (iii) More than 16 clients; or (iv) Fewer than 16 clients within a multi-unit building.	§483.430(c)(2) FACILITY PRACTICES: Staff are awake and providing needed care and services for the types of individual living arrangements specified. Staff know how to handle emergency situations for the types of individual living arrangements specified. §483.430(c)(2) GUIDELINES: The test of adequacy about "awake" staffing is how well the facility has organized itself to detect and react to potential emergencies, such as fire, injuries, health emergencies described in the medical care plan (e.g., aspiration, cardiac or respiratory failure, uncontrolled seizures) and behavioral crises described in the IPP. §483.420(c)(2) PROBES: Are there incidences of aggression, assault, or individuals leaving the building at night, without immediate detection?

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W184	(3) There must be a responsible direct care staff person on duty on a 24 hour basis (when clients are present) to respond to injuries and symptoms of illness, and to handle emergencies, in each defined residential living unit housing- - (i) Clients for whom a physician has not ordered a medical care plan; (ii) Clients who are not aggressive, assaultive or security risks; and (iii) Sixteen or fewer clients.	§483.430(c)(3) FACILITY PRACTICES: Staff are available and know how to respond to individual needs and emergencies at all times. §483.430(c)(3) GUIDELINES: The intent of the regulation is that at all times a staff person is in a position to help if individual needs arise. For purposes of this provision, "on duty" staff need not be awake during normal bedtime hours. Facilities sending some or all of the individuals to out of home or off grounds active treatment programs for a majority of the day need not provide a full complement of direct care staff in the residence during their absence. However, a minimum of one staff person must be on duty, if even one individual is present.
W185	(4) The facility must provide sufficient support staff so thatdirect care staff are not required to perform support services to the extent that these duties interfere with the exercise of their primary direct client care duties.	§483.430(c)(4) FACILITY PRACTICES: Direct care staff are not diverted from their primary direct care duties to performsupport functions (e.g., making beds, cooking, cleaning, etc.) when individual needs and programming require their presence and involvement. §483.430(c)(4) GUIDELINES: "Support staff" include all personnel hired by the facility that are not either direct care staff or professional staff. For example, support staff include, but are not limited to, secretaries, clerks, housekeepers, maintenance and laundry personnel. Direct care staff should be utilized at their highest level of competence, but they may assume other roles as long as their ability to exercise their primary direct care duties is not diluted. For example, direct care staff may serve as aides in a training program during the hours individuals are away from the living unit. §483.430(c)(4) PROBES: Is there observational or other evidence to suggest that individuals are being neglected (e.g., demonstrate need for toileting, changing, active treatment interventions) while staff do laundry, housekeeping, cooking or serving household tasks?
	(d) Standard: Direct care residential living unit staff.	
W186	(1) The facility must provide sufficient direct care staff to manage and supervise clients in accordance with their individual program plans.	§483.430(d)(1) FACILITY PRACTICES: There are sufficient numbers of direct care staff over and above minimum ratios to meet individual's needs and to implement the active treatment program as defined in the IPP. There are sufficient numbers of direct care staff to provide needed care and services

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		so that individuals do not injure themselves, others, or destroy property. Special staffing needs identified by the IPP (e.g., 1:1s) are provided. There are adequate numbers of direct care staff to supervise individuals during periods of time when other direct care staff are unavailable, e.g., breaks, meals, meetings, training, etc. §483.430(d)(1) GUIDELINES: "Sufficient" direct care staff means the number of staff, over and above the ratios specified in §483.430(d)(3), necessary to implement active treatment, as dictated by the individual's active treatment needs. Do not look at numbers alone. The facility is responsible for organizing and evaluating its individual appointments, programming schedules, activities, materials, equipment, grouping assignments and available staff in such a way that maximizes benefit to the individual. During the course of the onsite survey, you should be able to observe behavioral evidence of such organization. Evaluate this data in light of the success or failure observed relevant to providing active treatment, and come to a judgment about the adequacy of the facility's staffing.
	(2) Direct care staff are defined as the present on-duty staff calculated over all shifts in a 24-hour period for each defined residential living unit.	§483.430(d)(2) GUIDELINES: "Direct care staff" are those personnel whose daily responsibility it is to manage, supervise and provide direct care to individuals in their residential living units. This staff could include professional staff (e.g., registered nurses, social workers) or other support staff, if their primary assigned daily shift function is to provide management, supervision and direct care of individuals' daily needs (e.g., bathing, dressing, feeding, toileting, recreation and reinforcement of active treatment objectives) in their living units. However, professional staff who simply work with individuals in a living unit on a periodic basis cannot be included. Also, supervisors of direct care staff can be counted only if they share in the actual work of the direct care of individuals. Supervisors whose principal assigned function is to supervise other staff cannot be included.

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W187	(3) Direct care staff must be provided by the facility in the following minimum ratios of direct care staff to clients: (i) For each defined residential living unit serving children under the age of 12, severely and profoundly retarded clients, clients with severe physical disabilities, or clients who are aggressive, assaultive, or security risks, or who manifest severely hyperactive or psychotic-like behavior, the staff to client ratio is 1 to 3.2; (ii) For each defined residential living unit serving moderately retarded clients, the staff to client ratio is 1 to 4; (iii) For each defined residental living unit serving clients who function within the range of mild retardation, the staff to client ratio is 1 to 6.4.	§483.430(d)(3) GUIDELINES: The minimum ratios in this standard indicate the minimum number of direct-care staff that must be present and on duty, 24 hours a day, 365 days a year, for each discrete living unit. It does not include anyone functioning as direct care staff. For example, to calculate the minimum number of living unit staff that must be present and on duty in a discrete living unit serving 16 individuals with multiple disabilities: divide the number of individuals "16", by the number corresponding to the regulation "3.2", the result equals "5". Therefore, the facility must determine how many staff it must hire to ensure that at least 5 staff will be able to be present and on duty during the 24 hour period in which those individuals are present. Using the living unit described above, "calculated over all shifts in a 24-hour period" means that there are present and on duty every day of the year: one direct care staff for each eight individuals on the first shift (1:8), one direct care staff for each eight individuals on the second shift (1:8), and one direct care staff for each 16 individuals on the third shift (1:16). Therefore, there are five (5) direct care staff present and on duty for each twenty-four hour day, for 16 individuals. The same calculations are made for the other ratios, whichever applies. Determine if absences of staff for breaks and meals results in a pattern of prolonged periods in which present and on-duty staff do not meet the ratios.
W188	(4) When there are no clients present in the living unit, a responsible staff member must be available by telephone.	
	(e) Standard: Staff training program.	
W189	(1) The facility must provide each employee with initial and continuing training that enables the employee to perform his or her duties effectively, efficiently, and competently.	§483.430(e)(1) FACILITY PRACTICES: Staff have received training, both upon hiring and on an ongoing basis, which results in the competencies needed to do their job. §483.430(e)(1) PROBES: Is there an observed systemic lack of appropriate interactions and interventions with individuals? Does interview of staff and review of inservice records confirm little or no training activities? Does new staff receive orientation to the facility and the individuals with whom they are to work?

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	(2) For employees who work with clients, training must focus on skills and competencies directed toward clients'	§483.430(e)(2) GUIDELINES: View inservice training as a dynamic growth process. It is predicated on the view that all levels of staff can share competencies which enable the individual to benefit from the consistent, wide-spread application of the interventions required by the individual's particular needs. In the final analysis, the adequacy of the inservice training program is measured in the demonstrated competencies of all levels of staff relevant to the individual's unique needs as well as in terms of the "affective" characteristics of the caregivers and the personal quality of their relationships with the individuals. Observe the staff's knowledge by observing the outcomes of good transdisciplinary staff development (i.e., in the principles of active treatment) in such recommended competencies as: o Respect, dignity, and positive regard for individuals (e.g., how staff refers to individuals, refer to W150); o Use of behavioral principles in training interactions between staff and individuals; o Use of developmental programming principles and techniques, e.g., functional training techniques, task analysis, and effective data keeping procedures; o Use of accurate procedures regarding abuse detection and prevention, restraints, medications, individual safety, emergencies, etc.; o Use of adaptive mobility and augmentative communication devices and systems to help individuals achieve independence in basic self-help skills; and o Use of positive behavior intervention programming. §483.430(e)(2) PROBES: Does the staff training program reflect the basic needs of the individuals served within the program? Does observation of staff interactions with individuals reveal that staff know how to alter their own behaviors to match needs and learning style of individuals served?
W190	developmental,	§483.430(e)(2) FACILITY PRACTICES: Staff are observed to demonstrate cross-cutting skills which are appropriate when training and interacting with any individual with developmental disabilities (e.g., shaping, breaking tasks into small steps, providing positive reinforcement, providing informal opportunities to practice skills, using appropriate materials, etc.).
W191	behavioral,	§483.430(e)(2) FACILITY PRACTICES: Staff are observed to demonstrate cross-cutting skills and interactions which are effective in addressing inappropriate behavior and in supporting appropriate behavior for any individual (e.g., teaching and reinforcing positive, adaptive or incompatible behaviors, diffusion strategies, environmental manipulation, differential reinforcement of other behaviors (DRO), differential reinforcement of incompatable behaviors (DRI), physical management techniques, etc.).

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W192	and health needs.	§483.430(E)(2) FACILITY PRACTICES: Staff display the knowledge and competence to address the health and emergency medical needs of the individuals residing in the facility.
W193	(3) Staff must be able to demonstrate the skills and techniques necessary to administer interventions to manage the inappropriate behavior of clients.	§483.430(e)(3) FACILITY PRACTICES: Staff have the knowledge to correctly and consistently implement the intervention techniques specified in the behavior plans of individuals with whom they are working. §483.430(e)(3) GUIDELINES: Observe staff interactions with individuals to see if the specific interventions, techniques and strategies to change inappropriate behavior outlined in the sampled individual's program plans are correctly implemented. In the absence of implementation, investigate further to determine if there was a justifiable reason for not implementing an intervention (e.g., the plan was revised, the specific situation demanded a different approach, the conditions for use of a particular technique were not present, etc.) When staff are unable to demonstrate how to correctly implement an intervention, or are unable to explain when and how the intervention is to be implemented, inadequate training is evident.
W194	(4) Staff must be able to demonstrate the skills and techniques necessary to implement the individual program plans for each client for whom they are responsible.	§483.430(e)(4) FACILITY PRACTICES: Staff have the knowledge to correctly and consistently implement the specific IPPs of the individuals with whom they are working. §483.430(e)(4) GUIDELINES: Observe whether or not staff are competent and knowledgeable about the needs, programs and progress of each sampled individual with whom they are assigned to work. Staff should be able to demonstrate in practice the results of training for the individuals for whom they are responsible. See guidelines at §483.430(e)(3).

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W195	'483.440 Condition of participation: Active treatment services.	§483.440 COMPLIANCE PRINCIPLES: The Condition of Participation of Active Treatment Services is met when: o Individuals have developed increased skills and independence in functional life areas (e.g., communication, socialization, toileting, bathing, household tasks, use of community, etc.); o In the presence of degenerative or other limiting conditions, individuals' functioning is maintained to the maximum extent possible; o Individuals receive continuous, competent training, supervision and support which promotes skills and independence; and o Individuals need continuous, competent training, supervision and support in order to function on a daily basis. The Condition of Participation of Active Treatment Services is not met when: o Individuals functional abilities have decreased or have not improved and the facility has failed to identify barriers and implement a plan to minimize or overcome barriers; o Individuals are not involved in activities which address their individualized priority needs; o Individuals do not have opportunities to practice new or existing skills and to make choices in their daily routines; or o Individuals are able to function independently without continuous training, supervision and support by the staff.
	(a) Standard: Active treatment.	
W196	(1) Each client must receive a continuous active treatment program, which includes aggressive, consistent implementation of a program of specialized and generic training, treatment, health services and related services described in this subpart, that is directed toward-- (i) The acquisition of the behaviors necessary for the client to function with as much self determination and independence as possible; and (ii) The prevention or deceleration of regression or loss of current optimal functional status.	§483.440(a)(1) FACILITY PRACTICES: When viewed as a whole, the active treatment program is pervasive, systematic and sufficient in scope to assure that individuals are appropriately served. The major elements of the active treatment process are present and functioning in a consistent, cohesive manner including: o Each individual's needs and strengths have been accurately assessed and relevant input has been obtained from team members; o Each individual's IPP is based on assessed needs and strengths and addresses major life areas essential to increasing independence and ensuring rights; o Identified priority needs are addressed formally and through activities which are relevant and responsive to individual need, interest and choice; o Active treatment is consistently implemented in all relevant settings both formally and informally as the need arises or opportunities present themselves; o Each individual receives aggressive and consistent training, treatment, and services by trained staff in accordance with their needs and the IPP; o New skills and appropriate behaviors are encouraged and reinforced; o Each individual has the adaptive equipment and assistive technology necessary for him/her to function with increased independence; o Individual's routines and environments are organized to facilitate acquisition of skills, appropriate behavior, greater independence and choice;

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		o Each individual's performance is accurately measured and programs are modified based on data and major life changes; and o Individuals with degenerative conditions receive training, treatment and services designed to maintain skills and functioning and to prevent further regression to the extent possible. §83.440(a)(1) GUIDELINES: "Continuous" is defined to mean the competent interaction of staff with individuals served at all times, whenever the need arises or opportunities present, in both formal and informal settings. Verify that active treatment is identifiable during formal and informal interactions between staff and individuals served. The performance of the individual should reflect the success, if any, of interventions being applied or the need to alter the intervention procedures. The ICF/MR ensures that each individual receives active treatment daily regardless of whether or not an outside resource(s) is used for programming (e.g., public school, day habilitation center, senior day services program, sheltered workshop, supported employment). Those "active" interventions necessary to prevent or decelerate regression are considered to be part of the overall active treatment program. For example, if the application of a specific stimulation technique to the area of the mouth of an individual with severe physical and medical disabilities, decelerates the individual's rate of reliance on tube feedings, and helps the individual retain ability to take food by mouth, then this intervention is considered to be a component of active treatment for the individual. Active treatment for elderly individuals may increasingly need to focus on interventions and activities which promote physical wellness and fitness, socialization and tasks that stress maintaining coordination skills and reducing the rate of loss of skills that accompanies the physical aspects of the aging process. Attending a senior center may be a justifiable part of an active treatment program for an elderly person. Active treatment is the sum total of the major components of the active treatment process or loop which make up the requirements under this Condition of Participation (i.e., assessment, individual program planning, implementation, program documentation, program monitoring and change). It defines the primary nature of the services which must be provided by a facility (and received by its clients) in order to make it eligible under the law to be "certified" as an ICF/MR. Active treatment results in the positive outcomes identified by the Condition-level compliance principles. Surveyors must examine and evaluate all negative findings related to active treatment, and if determined to be significant, those findings should be cited at the salient tag numbers related to each of the components of the active treatment process. When review of

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		those deficiencies leads to the conclusion that active treatment is not being received, then this standard and the explicit statutory requirement for active treatment at '1905(d)(2) of the Social Security Act are not met. A determination of noncompliance with this requirement, therefore, must also result in a determination of noncompliance at the Condition of Participation level for Active Treatment Services and at §440.150(c), tag number W100. Although the active treatment process must be identifiable in documentation, it must be observable in daily practice. Determine how the ICF/MR accomplishes (or fails to accomplish) an environment of competence that enables active treatment to occur. SURVEY PROCEDURE: Record each observation done of individuals served by the facility. The optional Client Observation Worksheet (HCFA-3070-I) is the mechanism by which answers to identified data probes may be recorded. The worksheet is applicable to any observation, regardless of whether or not the individual is part of the representative random sample. See Task 3, pages J-7-8, for instructions for completing observations. §483.440(a)(1) PROBES: How does the facility address the active treatment needs of individuals along their full life span? As you conduct each observation, determine: o Is the activity scheduled or planned? o Are materials present to implement the activity? o Are they used? o Are all individuals present involved or engaged in the activity? o Are the activity and materials age-appropriate, adaptive and functional? o Are new skills and behaviors being taught or reinforced? o Are all individuals reinforced and prompted frequently? o Are all staff verbally and physically involved? o Are there sufficient staff for the activity? o Are interactions characterized by a "mentor/friend" tone? Does the activity relate directly to specific objectives and needs? Do staff demonstrate the skills necessary to train or reinforce training on the IPP objectives? o Are individuals observed to engage in aggression, self-injurious behavior or self-stimulatory behavior (e.g., finger flicking)? If so, do staff intervene as per the IPP?
W197	(2) Active treatment does not include services to maintain generally independent clients who are able to function with little supervision or in the absence of a continuous active treatment program.	§483.440(a)(2) FACILITY PRACTICES: As a practice, the facility does not serve individuals who, to a large extent, are able to care for their own basic needs, require minimal supervision and do not require the structure, support and resources of a comprehensive service program on an ongoing basis.

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		§483.440(a)(2) GUIDELINES: The regulations define the target population eligible for the ICF/MR benefit, by defining the services that are required for a facility to provide in order for it to qualify as an ICF/MR and receive Federal Financial Participation (FFP). At the front end, one of the "required services" is training in basic fundamental skills. The type of skills described in W242, by their very nature, target a population who have significant deficits in growth and development. The presence of any group of individuals (court-ordered or not), could call into question the overall nature of the services provided by the ICF/MR. Individuals displaying some or all of the characteristics described in the Interpretive Guideline at '483.440(b)(1), do not "need active treatment services" or ICF/MR level of care, and are not appropriately placed. Agencies which provide residential services to persons with mental retardation do not qualify automatically for participation in Medicaid as ICFs/MR. Although the facility may be providing services to meet the needs of these types of individuals, the services provided by the facility do not meet the regulatory definition of "active treatment." Furthermore, if the primary purpose of the facility is no longer to provide services to persons with mental retardation or related conditions who are in need of active treatment, then the facility does not meet the statutory requirement at '1905(d) of the Social Security Act and the regulatory definition of an ICF/MR, and therefore cannot be certified. A determination of noncompliance with this requirement, therefore, must result in a determination of noncompliance at the Condition of Participation level and at '440.150(c). Conversely, if the overall facility meets the definition of an ICF/MR, the law does tolerate the presence of a few individuals for whom payment cannot be claimed. If an entity must serve both people who are generally independent and people who are in need of active treatment, then the entity may need to consider establishing a distinct part ICF/MR to serve those individuals who are in need of active treatment. Negative findings about active treatment with regard to generally independent clients may be in conflict with level of care determinations made by State inspection of care (IOC) teams. Bring these negative active treatment findings to the attention of the IOC agency within the State for appropriate disposition of Medicaid ICF/MR certification. (See also W198, if the negative findings involve newly admitted individuals.) There are some individuals who need the help of an ICF/MR to continue to function independently because they have learned to depend upon the programmatic structure it provides. The fact that they are not yet independent, even though they can be, makes it appropriate for them to receive active treatment services directed at achieving needed and possible independence.
	(b) Standard: Admissions, transfers, and discharge.	

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W198	(1) Clients who are admitted by the facility must be in need of and receiving active treatment services.	§483.440(b)(1) FACILITY PRACTICES: The facility has determined that each individual admitted into the ICF/MR benefit program since October 3, 1988, is in need of a program of active treatment. Each individual needing active treatment receives it from the time of their admission to the facility. §483.440(b)(1) GUIDELINES: Individuals with the following characteristics do not necessarily require a continuous active treatment program in order to function or to achieve optimal independence. Review closely to what extent the ICF/MR serves individuals, who in the aggregate: o Are independent without aggressive and consistent training; o Are usually able to apply skills learned in training situations to other settings and environments; o Are generally able to take care of most of their personal care needs, make known to others their basic needs and wants, and understand simple commands; o Are capable of working at a competitive wage level without support, and to some extent, are able to engage appropriately in social interactions; o Are engaged in productive work within the facility which is done at an acceptable level of independence (i.e., not done as part of a training program to teach the individual new skills); o Are able usually, to conduct themselves appropriately when allowed to have time away from the facility's premises; and o Do not require the range of professional services or interventions in order to make progress. Based on the order of a court, the ICF/MR may be required to admit individuals who do not need active treatment. Although HCFA has no jurisdiction to prevent the courts from ordering the placements of such individuals into institutions certified as ICFs/MR, the individuals, by definition, would be ineligible to be classified by Medicaid for the ICF/MR benefit. To the extent that the placement of these court-ordered individuals does not interfere with the ability of the ICF/MR to provide active treatment for its individuals, the facility's overall certification is not affected.
W199	(2) Admission decisions must be based on a preliminary evaluation of the client that is conducted or updated by the facility or by outside sources.	§483.440(b)(2) FACILITY PRACTICES: A preliminary evaluation to determine the need for active treatment is conducted, obtained or updated. The information from the preliminary evaluation is used by the facility to make an admission decision. §483.440(b)(2) GUIDELINES: No admission should be regarded as permanent. Readmission of an individual to the ICF/MR falls under the same requirements as initial admission.

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		In the absence of State regulations designating the person(s) authorized to approve admission (e.g., State or Regional Admissions Committees), the decision to admit an individual to the ICF/MR is based on the findings of an interdisciplinary team, including a QMRP. Occasionally, emergency admissions of individuals may occur without benefit of a preliminary evaluation having been conducted prior to admission. For purposes of '483.440(b)(2) and consistent with '456.370(a), this requirement will be considered as "met" at such time that an evaluation is conducted which supports the need for an individual's placement in the ICF/MR. Refer to W210.
W200	(3) A preliminary evaluation must contain background information as well as currently valid assessments of functional developmental, behavioral, social, health and nutritional status to determine if the facility can provide for the client's needs and if the client is likely to benefit from placement in the facility.	§483.440(b)(3) FACILITY PRACTICES: Information in the preliminary evaluation accurately describes the individual. The preliminary evaluation contains specific information that identifies the individual's needs and whether or not the facility has the ability to respond to those needs in a manner which is likely to benefit the individual. §483.440(b)(3) GUIDELINES: The facility must decide, based on objective data, whether or not needs can be met. In some cases, the facility may be required to meet the "reasonable accommodation" requirement of the Americans with Disabilities Act. Failure to admit individuals merely because they have a particular medical condition may constitute a civil rights violation. All such instances should be reported to the Office of Civil Rights for investigation.
	(4) If a client is to be either transferred or discharged, the facility must- -	
W201	(i) Have documentation in the client's record that the client was transferred or discharged for good cause; and	§483.440(b)(4)(i) FACILITY PRACTICES: Transfer or discharge occurs only when the facility cannot meet the individual's needs, the individual no longer requires an active treatment program in an ICF/MR setting, the individual/guardian chooses to reside elsewhere, or when a determination is made that another level of service or living situation, either internal or external, would be more beneficial, or for any other "good cause," as defined below. §483.440(b)(4)(i) GUIDELINES: "Transfer" means the temporary movement of an individual between facilities, the temporary movement from the ICF/MR to a psychiatric or medical hospital for medical reasons, the permanent movement of an individual between living units of the same facility, or the permanent movement of an entire facility (including individuals served, staff and records) to a new location. "Discharge" means the permanent movement of an individual to another facility or setting which operates independently from the ICF/MR. Moving an individual for "good cause" means for any reason that is in the best interest of the individual.

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		§483.440(b)(4)(i) PROBES: Can you identify a pattern of transfer or discharge that occurs suddenly and that cannot be accounted for on an emergency basis? What are the facility's criteria for emergency transfer or discharge and what are the procedures? Do parents/family members/friends/advocates/guardians participate with the individual in the transfer/discharge decision-making process? Does the reason for transfer/discharge given by the individual and/or family correspond with what is reported in the record?
W202	(ii) Provide a reasonable time to prepare the client and his or her parents or guardian for the transfer or discharge (except in emergencies).	§483.440(b)(4)(ii) FACILITY PRACTICES: The individual and the family or guardian are involved in planning for movement. The individual and the family or guardian receive the services necessary to assist in preparing for movement, unless an emergency situation prevents that involvement. §483.440(b)(4)(ii) GUIDELINES: The family and the individual should be involved in any decision to move an individual, since this decision generally, should be part of a team process that includes the individual or guardian. If an individual has an advocate, the advocate should participate in the decision-making process. §483.440(b)(4)(ii) PROBES: What do individuals who are being considered for transfer/discharge (and/or parents, etc.) report about their participation in the process (if any)? Does the IPP reflect objectives preparing the individual for transfer or community placement? How are individual and family views recognized by facility staff? How do they deal with them?
	(5) At the time of the discharge, the facility must- -	
W203	(i) Develop a final summary of the client's developmental, behavioral, social, health and nutritional status	§483.440(b)(5)(i) FACILITY PRACTICES: A final summary is developed. The final summary accurately describes the individual, including his/her strengths, needs, required services, social relationships and preferences.

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W204	and, with the consent of the client, parents (if the client is a minor) or legal guardian, provide a copy to authorized persons and agencies; and	§483.440(b)(5)(i) FACILITY PRACTICES: The final summary is released only with the consent of the legally appropriate party.
W205	(ii) Provide a post-discharge plan of care that will assist the client to adjust to the new living environment.	§483.440(b)(5)(ii) FACILITY PRACTICES: Information in the post-discharge plan is sufficient to allow the receiving facility to provide the services and supports needed by the individual in order to adjust to the new placement. The facility supports and assists the individual in this transfer. §483.440(b)(5)(ii) GUIDELINES: The discharge plan required by 42 CFR 456.380 and the "post-discharge plan of care are the same. The regulations require only one discharge plan which meets the requirements.
	(c) Standard: Individual program plan.	
W206	(1) Each client must have an individual program plan developed by an interdisciplinary team that represents the professions, disciplines or service areas that are relevant to- - (i) Identifying the client's needs, as described by the comprehensive functional assessments required in paragraph (c)(3) of this section; and (ii) Designing programs that meet the client's needs.	§483.440(c)(1) FACILITY PRACTICES: The individual's interdisciplinary team is composed of those individuals (professionals, paraprofessionals and non-professionals) who possess the knowledge, skills and expertise necessary to accurately identify the comprehensive array of the individual's needs and design a program which is responsive to those needs. §483.440(c)(1) GUIDELINES: There is no "correct" number of individuals who comprise the interdisciplinary team. The regulation also does not specify the professional disciplines which make up the interdisciplinary team. Based upon outcomes, assess whether the expertise available to the team was appropriate to meet the needs of the individual. The facility must make every effort to coordinate the IEP or program plan from an outside day program with the IPP process. This may result in a single IEP/IPP document, but there is no requirement for the IPP to be one document. The "collective" IPP must contain the information required under the regulations, and observation should confirm integration of the IPP across the various settings. Negative answers to the following probes may indicate a lack of input from appropriate team members. Evaluate findings for systemic lack of input by a particular team member, lack of communication among team members, or lack of team effort and cooperation.

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		§483.440(c)(1) PROBES: Do the plans from individual to individual have a predictable sameness about them? Does the plan flow from only original diagnosis/assessment? Does it take into consideration interim progress or emergent needs? Does the team create an integrated plan or is the plan a "stapling together" of individual pieces with little or no discussion as to how pieces relate/impact on each other? Are conflicts seen among various pieces of the plan? Refer to W120. When prepackaged programs are used, are needed individual adaptations tailored to the needs, and functional skills of an individual?
W207	(2) Appropriate facility staff must participate in interdisciplinary team meetings.	§483.440(c)(2) GUIDELINES: Meetings should be scheduled and conducted to facilitate the participation of all members of the team, but especially the individual, unless he or she is clearly unable or unwilling, the individual's parents (except in the case of a competent adult who does not desire them to do so) or the individual's guardian or legal representative. The ICF/MR is expected to pursue aggressively the attendance of all relevant participants at the team meeting, (e.g., a conference call with a consultant during deliberations meets this requirement). Question routine "unscheduled" absences by individuals, guardians and particular disciplines or consultants, and determine the impact on effectiveness and responsiveness of the IPP to meet the individual's needs. §483.440(c)(2) PROBES: Does the facility have a working means of gathering all needed data for IPP sessions? Are the views of staff not present at the team meeting incorporated in the plan? Are individuals/parents/guardians provided with information prior to a meeting which will be used at the meeting to make decisions? Does the scheduling of the program planning meeting take into account the schedules of day programs and the availability of family? If unable to attend, does someone review the results of meetings, and act on areas of question, dispute? If individuals served do not attend IPP meetings, what reasons do staff give to explain their absence? How does staff prepare individuals to participate in interdisciplinary team meetings? Does the facility respect individual wishes for additional representatives on the interdisciplinary team, such as friends or advocates?
W208	Participation by other agencies serving the client is encouraged.	
W209	Participation by the client, his or her parent (if the client is a minor), or the client's legal guardian is required unless the participation is unobtainable or inappropriate.	

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W210	(3) Within 30 days after admission, the interdisciplinary team must perform accurate assessments or reassessments as needed to supplement the preliminary evaluation conducted prior to admission.	§483.440(c)(3) FACILITY PRACTICES: For new admissions, the assessment is completed within 30 days of admission. New, revised or updated assessments accurately identify the functional abilities of the individual (whether or not that individual is a new admission). Observations and interviews confirm the accuracy of these assessments. §483.440(c)(3) GUIDELINES: "Accurate" assessments refer to assessment data that are current, relevant and valid, and that the skills, abilities, and training needs identified by the assessment correspond to the individual's actual status. Additionally, for assessment data to be accurate, the cultural background and experience of the individual must be reflected in the choice, administration and interpretation of the evaluation(s) used. A few examples of appropriate adaptations might be: specialized equipment, use of an interpreter, use of manual communication, tests designed to measure performance in the presence of visual disability, etc. The contents of assessments or the particular assessment which must be used are not specified. A nursing assessment, for example, would not need to reference all domains, or a psychiatric or psychological evaluation would not necessarily have to be based on a particular "tool". Similarly, the results of the comprehensive assessment are not required to be written into a narrative report(s). Verify that the tests, evaluations, etc. that comprise the comprehensive functional assessment, yield data that are accurate, reflect the current status and needs of the individual, and can serve as a functional basis for an IPP to be developed.
	The comprehensive functional assessment	
W211	must take into consideration the client's age (for example, child, young adult, elderly person) and the implications for active treatment at each stage, as applicable, and must- -	§483.440(c)(3) FACILITY PRACTICES: Assessments address areas and active treatment needs which are relevant to the person's chronological age. The individual is given opportunities to participate in age-appropriate activities to assess the person's functioning in those activities or settings. §483.440(c)(3) GUIDELINES: The active treatment assessment process should be sensitive to the behaviors of individuals throughout their life span. For example, infants and toddlers are expected to engage in more play-related, exploratory activities, adolescents are expected to engage in activities of increasingly greater responsibility in preparation for adulthood, adults are expected to support themselves or at least be engaged in training or education activities toward that end, and elderly citizens, are expected to choose whichever form of productive activity meets their needs and interests (employment, handiwork, pursuit of leisure, etc.) for as long as they are able.

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W212	(i) Identify the presenting problems and disabilities and where possible, their causes;	§483.440(c)(3)(i)--(iv) FACILITY PRACTICES: Diagnoses are present, when applicable. Diagnoses are based on relevant, objective and accurate data. Diagnoses are modified as accurate, relevant, and updated as medical or other professional information becomes available. §483.440(c)(3)(i) GUIDELINES: In the presence of a diagnoses (medical or otherwise), evaluation data must be available to support the determination.
W213	(ii) Identify the client's specific developmental strengths;	§483.440(c)(3)(ii) FACILITY PRACTICES: The individual's preferences, methods of coping/compensation, friendships and positive attributes are clearly described in functional terms in assessments. Identified strengths are current, complete and consistent with the individual's observed functional status.
W214	(iii) Identify the client's specific developmental and behavioral management needs;	§483.440(C)(3)(iii) FACILITY PRACTICES: The individual's needs, skill deficits, and functional limitations are clearly described in functional terms in the assessments. Identified needs are current, accurate, complete and reflect the individual's observed functional status. §483.440(C)(3)(ii-iii) GUIDELINES: The comprehensive functional assessment (CFA) may be a report synthesizing the results of salient assessments or a series of reports. If individual reports are utilized, the complete diagnostic work-up or problem list identified by others is not required to be repeated unless it is relevant to the particular assessment. Findings are recorded in terms that facilitate clear communication across disciplines. Diagnoses or imprecise terms and phrases (including, but not limited to, "grade level," "age level," "developmental level," "good attending skills," and "poor motor ability") in the absence of specific terms, are not acceptable. Assessment of the behavior assumed to be maladaptive should include analyses of the potential causes, such as lack of exposure to positive models and teaching strategies, lack of ability to communicate needs and desires, lack of success experiences, a history of punishing experiences, presence of a physiological condition, or other environmental or social conditions which may elicit or sustain the behavior. Specific "developmental" strengths and needs describe what the individual "can" and "cannot" do.

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		§483.440(c)(3)(i)--(iii) PROBES: Do assessments interpret the significance of the results in terms of the individuals' functional daily life needs or do they simply describe diagnoses, test performances or clinical impressions? Do assessments merely report scores or functioning age levels or in the absence of strengths/needs lists, are the skills necessary to support those determinations identified within the assessment? Do the strengths and needs identified by the facility correspond to what you see individuals do or not do during observations? Does the assessment reflect how the environment could be changed to support the person?
W215	(iv) Identify the client's needs for services without regard to the actual availability of the services needed; and	§483.440(c)(3)(iv) FACILITY PRACTICES: Identification of needed services is based on the comprehensive functional assessment. Recommendations are present to address areas of deficits. §483.440(c)(3)(iv) GUIDELINES: In the presence of significant developmental deficits, it is not acceptable for the comprehensive evaluation to identify that a particular professional therapy or treatment is not needed. To meet the requirement for "need for service," the assessment must identify the course of specific interventions recommended to meet the individual's needs in lieu of direct professional therapy or treatment. §483.440(c)(3)(iv) PROBES: Do assessments conclude whether or not "hands-on" therapy conducted by professionals is indicated, and if an individual problem still exists, does the assessment recommend how the team should deal with the problem? Is there a pattern of individual need areas not addressed in individuals' IPP objectives that correspond to the absence of those professional service areas at the facility?
	(v) Include	§483.440(c)(3)(v) FACILITY PRACTICES: Assessment of each area is present. Assessment of each area provides specific information about the person's ability to function in different environments, specific skills or lack of skills, and how function can be improved, either through training, environmental adaptations, or provision of adaptive, assistive, supportive, orthotic, or prosthetic equipment. §483.440(c)(3)(v) GUIDELINES: The facility must assess in developmental areas, but not by professional disciplines unless the functional assessment shows a need for a full professional evaluation. Findings relative to the domains required under '483.440(c)(3)(v) include, but are not

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		limited to:
W216	physical development and health,	1. Physical development and health. Physical development includes the individual's developmental history, results of the physical examination conducted by a licensed physician, physician assistant, or nurse practitioner, health assessment data (including a medication and immunization history), which may be compiled by a nurse, and skills normally associated with the monitoring and supervision of one's own health status, and administration and or scheduling of one's own medical treatments. When indicated by physical examination results, consultations by specialists are provided or obtained. The need for advance directives or do not resuscitate (DNR) orders may be assessed on a case-by-case basis, as part of this area by individuals qualified to do so.
W217	nutritional status,	2. Nutritional status. Nutritional status includes determination of appropriateness of diet, adequacy of total food intake, and the skills associated with eating, (including chewing, sucking and swallowing disorders), food service practices, and monitoring and supervision of one's own nutritional status.
W218	sensorimotor development,	3. Sensorimotor development: Sensory development includes the development of perceptual skills that are involved in observing the environment and making sense of it. Motor development includes those behaviors that primarily involve: muscular, neuromuscular, or physical skills and varying degrees of physical dexterity. Because sensory and motor development are intimately related, and because activities in these areas are functionally inseparable, attention to these two aspects of bodily activity is often combined in the concept of sensorimotor development. Assessment data identify the extent to which corrective, orthotic, prosthetic, or support devices would impact on functional status.
W219	affective development,	4. Affective (Emotional) development. Affective or emotional development includes the development of behaviors that relate to one's interests, attitudes, values, and emotional expressions.
W220	speech and language development	5. Speech and language (communication) development. Communication development refers to the development of both verbal and nonverbal and receptive and expressive communication skills. Assessment data identify the appropriate intervention strategy to be applied, and which, if any, augmentative or assistive devices will improve communication and functional status.
W221	and auditory functioning,	6. Auditory functioning. Auditory functioning refers to the extent to which a person can hear and to the maximum use of residual hearing if a hearing loss exists and whether or not the individual will benefit from the use of amplification, including a hearing aid or a program of amplification. An individual's treatment might need to include being desensitized to tolerate the use of a hearing aid or assistive listening device to prevent the device from being rejected or destroyed. Assessment may include teaching techniques for conducting the assessment or the use of electrophysiologic techniques.

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W222	cognitive development,	7. Cognitive development. Cognitive development refers to the development of those processes by which information received by the senses is stored, recovered, and used. It includes the development of the processes and abilities involved in memory, reasoning and problem solving.
W223	social development,	8. Social Development. Social development refers to the formation of those self-help, recreation and leisure, and interpersonal skills that enable an individual to establish and maintain appropriate roles and fulfilling relationships with others.
W224	adaptive behaviors or independent living skills necessary for the client to be able to function in the community,	9. Adaptive behaviors or independent living skills. Adaptive behavior refers to the effectiveness or degree with which individuals meet the standards of personal independence and social responsibility expected of their age and cultural group. Independent living skills include, but are not limited to, such things as meal preparation, doing laundry, bedmaking, and budgeting. Assessment may be performed by anyone trained to do so. Standardized tests are not required. Standardized adaptive behavior scales which identify all or predominantly all "developmental needs" are not sufficient enough to meet this requirement, but can serve as a basis for screening.
W225	and as applicable, vocational skills.	10. Vocational (prevocational) development, "as applicable". Vocational development refers to work interests, work skills, work attitudes, work-related behaviors, and present and future employment options. The determination of whether or not a vocational assessment is "applicable" is typically based on age (adolescents or adults more than likely require this type of assessment). §483.440(c)(3)(v) PROBES: For all domains, do assessments describe what individuals can and cannot do in terms of skills needed within the context of their daily lives? Is the assessment based on: o Actual performance of the individual against objectified criteria? o Reports by staff/parents/guardians? o Observed performance in a variety of settings? o Simple checklists? Are assessments individualized? Are assessments conducted in appropriate environments?
W226	(4) Within 30 days after admission, the interdisciplinary team must prepare for each client an individual program plan	

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W227	that states the specific objectives necessary to meet the client's needs, as identified by the comprehensive assessment required by paragraph (c)(3) of this section,	§483.440(c)(4) FACILITY PRACTICES: The IPP contains a list of specific objectives based on needs identified in the CFA. There is a clear link between the specific objectives and the functional assessment data and recommendations. Objectives are developed for those needs that are observed to most likely impact on the individual's ability to function in daily life. §483.440(c)(4) GUIDELINES: The presence of a comprehensive list of behaviorally stated needs is acceptable for this portion of the requirement. "Comprehensive" means that objectives are stated for the needs identified in each domain included in the comprehensive functional assessment. Objectives may address services to be provided, learning/treatment needs, adaptive equipment, etc. "483.440(c)(4)(i)-(v) regulate requirements for current IPP training objectives (as opposed to staff, service, or long term objectives). Validate that the needs identified by the team are appropriate for the individual based upon review of the comprehensive functional assessment data, observations, and interviews with the individual and staff. §483.440(c)(4) PROBES: Is there a predominant pattern of staff-oriented objectives rather than learner-oriented objectives? Is there repetition and predictability of programming across individuals?
W228	and the planned sequence for dealing with those objectives.	§483.440(c)(4) FACILITY PRACTICES: The objectives identified in W227 are arranged in a sequence identifying the logical order in which they will be addressed. Objectives are organized in a sequence relevant to the individual's long term development. §483.440(c)(4) GUIDELINES: To organize objectives into a planned sequence the ICF/MR must consider the outcomes it projects for the individual in the long term. For example, if the long term objective is for the individual to travel independently in the community, the planned sequence may involve training the individual to recognize traffic signs, cross a street safely, and to obtain help when needed if lost or an emergency arises. Interview staff to discover the purpose to be achieved upon completion of the objective. For example, does staff know why an individual is taught to stack rings?
	These objectives must- -	

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W229	(i) Be stated separately, in terms of a single behavioral outcome;	§483.440(c)(4)(i) FACILITY PRACTICES: Each objective clearly states one expected learning result. §483.440(c)(4)(i) GUIDELINES: "Single" behavioral outcome means that for each discrete behavior that the team intends the individual to learn a separate objective is assigned. (For example, "Mary will bake a cake and clean the oven" are two separate behaviors and, therefore, should be stated in two separate objectives.) Performance of a series of separate behaviors could constitute a single behavioral outcome when appropriate for the individual. For example, completing a hygiene routine of face washing, toothbrushing and haircombing is one behavioral outcome when the individual is able to perform each of those skills, but needs to learn to complete the entire routine each morning.
W230	(ii) Be assigned projected completion dates;	§483.440(c)(4)(ii) FACILITY PRACTICES: Completion dates are based on the individual's rate of learning. Completion dates are assigned to each objective on which the individual is currently working. Completion dates are individualized (i.e., not all the same for all clients and all objectives). §483.440(c)(4)(ii) GUIDELINES: The "projected date of completion" for an IPP objective is not the same as a "review" date. For each objective assigned priority, the team should assign a projected date (month and year) by which it believes the individual will have learned the new skill, based on all of the assessment data. This date triggers the team to evaluate continuously whether or not the individual's progress or learning curve is sufficient to warrant a revision to the training program. There is no requirement to identify an implementation date for each objective in the plan.
W231	(iii) Be expressed in behavioral terms that provide measurable indices of performance;	§483.440(c)(4)(iii) FACILITY PRACTICES: The learning outcome is stated in a manner which enables all staff working with the individual to consistently identify the target behavior and to clearly identify when it is being displayed. The objective is stated in a manner which permits it to be quantifiably measured. §483.440(c)(4)(iii) GUIDELINES: "Behavioral" terms include only those behaviors which are "individual" rather than "staff" oriented and those that any person would agree can be seen or heard. Determine if all staff who work with the individual can define the exact same outcome on which to measure the individual's performance. "Measurable indices of performance" are the quantifiable criteria to use in determining successful achievement of the objective. Criteria include various measurements of intensity and duration. For example, "M. will walk ten feet, with her tripod walker, for 5 consecutive days."

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W232	(iv) Be organized to reflect a developmental progression appropriate to the individual; and	§483.440(c)(4)(iv) FACILITY PRACTICES: Objectives and criteria for success are based on the individual's current or baseline functional abilities. Objectives are designed to allow the individual to experience success in achieving those objectives. Objectives are individualized to take into consideration the individual's abilities and disabilities. Objectives are organized to begin with the next logical step, given the individual's current functioning, and move toward more complex behavior. §483.440(c)(4)(iv) GUIDELINES: To organize an objective in an appropriate progression, the ICF/MR must consider the person's current functional abilities and project what steps, methods and strategies are likely to be effective in achieving the objective. Baseline data are one means of establishing an appropriate starting point for an objective. Objectives must be adapted based upon the person's functional abilities. For example, if the objective is to learn to put on shoes independently and the person does not have the manual dexterity to tie shoe laces, then the objective could include the use of slip-on shoes or shoes with velcro closures in order to facilitate the person learning this skill. §483.440(c)(4)(iv) PROBES: Are chosen objectives the most direct means for resolving identified needs? Do programs and strategies have a relationship to needs identified and objectives chosen?
W233	(v) Be assigned priorities.	§483.440(c)(4)(v) FACILITY PRACTICES: The IDT identifies which objectives are the most important to work on now. Skills and behaviors which significantly impact upon the individual's day-to-day functioning are worked on first. §83.440(c)(4)(v) GUIDELINES: After all the training objectives have been established as required by W227, the IPP identifies those objectives which the team considers to be most important, or which need to be implemented before others can be accomplished, and then assigns them priority. Some examples of assigning priority include, but are not limited to, rank ordering (most important to least important), assignment of "priority" or "non-priority", etc. §483.440(c)(4)(v) PROBES: Is there a pattern of most individuals' objectives having the same "prioritization" assignment (e.g., do most individuals have a number one objective as handwashing or

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		does the facility select a specific number of objectives of equal importance)? Are objectives and priorities based on each individual's needs?
	(5) Each written training program designed to implement the objectives in the individual program plan must specify:	§483.440(c)(5) GUIDELINES: The written training program refers only to those objectives to which the team has assigned priority status for formal implementation.
W234	(i) The methods to be used;	§483.440(c)(5)(i) FACILITY PRACTICES: The training program provides clear directions to any staff person working with the individual on how to implement the teaching strategies.
W235	(ii) The schedule for use of the method;	§483.440(c)(5)(ii) FACILITY PRACTICES: The training program provides clear directions to any staff person working with the individual about when the strategies are to be implemented.
W236	(iii) The person responsible for the program;	§483.440(c)(5)(iii) FACILITY PRACTICES: The person who will monitor the program and ensure it is being implemented appropriately, is clearly identified on the written training program. §483.440(c)(5)(iii) GUIDELINES: This may or may not be the same person who implements the program. There is no requirement to identify who implements the program.
W237	(iv) The type of data and frequency of data collection necessary to be able to assess progress toward the desired objectives;	§483.440(c)(5)(iv) FACILITY PRACTICES: The training program provides clear directions to any staff person working with the individual about the type of data to record, and the frequency which data is to be recorded. The data collection system is directly related to the outcome stated in the objective. §483.440(c)(5)(iv) GUIDELINES: The facility must determine the type of data necessary to judge an individual's progress on an objective, and describe that data collection method in the written training program. The facility determines what data to collect, but the system chosen must yield accurate measurement of the criteria stated in the individual's IPP objectives. For example, if the criteria in the individual's IPP objective specified some behavior to be measured by "accuracy," or "successes out of opportunities," then it would not be acceptable for the prescribed data collection method to record "level of prompt." Methods of data collection on IPP training programs should be based on the total (including direct care) facility's staff analysis and observations of an individual's behavior. Examples of a few data collection systems include, but are not limited to,

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		level of prompt, successful trials completed out of opportunities given, frequency counts, frequency sampling, etc. The facility should collect data with enough frequency and enough content that it can measure appropriately the individual's performance toward the targeted IPP objective.
W238	(v) The inappropriate client behavior(s), if applicable; and	§483.440(c)(5)(v) FACILITY PRACTICES: Any behaviors which would interfere with the individual's ability to function in, or benefit from the training program are identified.
W239	(vi) Provision for the appropriate expression of behavior and the replacement of inappropriate behavior, if applicable, with behavior that is adaptive or appropriate.	§483.440(c)(5)(vi) FACILITY PRACTICES: The training program provides specific information as to how to elicit or strengthen appropriate behavior and what behaviors to teach, reinforce or encourage which would reduce or replace the inappropriate behavior. Replacement behaviors are functionally related to the targeted behavior.
	(6) The individual program plan must also:	
W240	(i) Describe relevant interventions to support the individual toward independence.	§483.440(c)(6)(i) FACILITY PRACTICES: The IPP provides specific information to any staff person working with the individual about what services and supports they are to provide to assist the individual in functioning at a more independent level.
W241	(ii) Identify the location where program strategy information (which must be accessible to any person responsible for implementation) can be found.	§483.440(c)(6)(ii) FACILITY PRACTICES: Staff know where to find information about the programs to be implemented.
W242	(iii) Include, for those clients who lack them, training in personal skills essential for privacy and independence (including, but not limited to, toilet training, personal hygiene, dental hygiene, self-feeding, bathing, dressing, grooming, and communication of basic needs), until it has been demonstrated that the client is developmentally incapable of acquiring them.	§483.440(c)(6)(iii) FACILITY PRACTICES: All individuals who lack the skills listed have training programs designed to meet their needs. These programs are consistently implemented in both formal and informal settings. There is documentation of consistent, appropriate attempts to teach individuals these skills, or specific evidence as to a medical condition which would preclude acquisition, prior to determination of developmental incapability. Appropriate materials, adaptations and modifications to equipment and the environment are available in order to promote and support individual training programs. §483.440(c)(6)(iii) GUIDELINES: The receipt of training targeted toward amelioration of these most basic skill deficit

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		areas is a critical component of the active treatment program needed by individuals who are eligible for the ICF/MR benefit, and therefore, is a required ICF/MR service. Some ADL skills overlap with each other (e.g., personal hygiene, oral hygiene, grooming and bathing). It is acceptable for the interdisciplinary team to set priorities within these overlapping skills. It must be clear, however, that the facility has organized its services to emphasize training in these areas. This will be seen not only in the IPP, but also in the competent interaction of staff with individuals, in both formal and informal settings. This basic skill training defines the nature of ICF/MR services. To the extent that individuals demonstrate that they increasingly do not need the types of services described in this requirement, and increasingly correspond to the characteristics of clients described at W197 such that the "overall" nature of the facility services would not be required to provide the type of emphasis described at W242, question the appropriateness of the individual's placement in an ICF/MR and/or the certification of the facility as an ICF/MR (see W197 and W198). "Training" as used in this regulation means: o Aggressive implementation of a systematic program of formal and informal techniques (competent interactions); o Continuously targeted toward the individual achieving the measurable behavioral level of skill competency specified in IPP objectives; o Conducted in all applicable settings; and o Conducted by all personnel involved with the client. "Developmental incapability" is a decision to be made by the interdisciplinary team based on its assessment of the individual's developmental strengths and needs. For example, there is ample evidence that even individuals with the most severe physical and mental disabilities can be toilet trained. Recognition is given to the fact that some individuals, however, have insufficient sensory and neuromuscular control ever to be totally independent in toileting skills. For most of this group, there are intermediate steps which can be achieved, including toilet scheduling, in which the individual is able to be trained to a schedule of elimination with needed assistance from staff. The intent of the toileting part of this regulation is met if there is evidence that the individual has been provided an aggressive, well organized, and well executed toilet training program in the past and that the team determines the individual's "developmental incapability." §483.440(c)(6)(iii) PROBES: Is evidence of "developmental incapability" based on individual performance, medical evidence, historical efforts at training; or is it based on "opinions" of staff (in the absence of performance data)? Does the activity prepare individuals to function more independently or does it merely train the individual to adapt to his/her particular facility (e.g., large institutional living)? Do staff direct their activities toward the acquisition of individuals to learn increasingly complex skills or do staff accept that individuals will not or cannot grow and change?

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	(iv) Identify mechanical supports, if needed, to achieve proper body position, balance, or alignment. The plan must specify	§483.440(c)(6)(iv) GUIDELINES: Mechanical devices used to support an individual's proper body position or alignment may be essential to prevent contractures and deformities, but the staff should be sensitive to the fact that mechanical supports may restrict movement and the individual should not be in the supports all the time or as a substitute for programs or therapy which may reduce the dependency on the support. Some supports allow movement and provide opportunity for more increased functioning. Some examples of devices used as mechanical supports include splints, wedges, bolsters, lap trays, etc. Wheelchairs are not generally used to position or align the body and would not alone constitute a mechanical support. However, adaptations to wheelchairs which do position or align the body would have to be specified according to this requirement. Adaptations to a wheelchair which facilitate correct body alignment by inhibiting reflexive, involuntary motor activity are also mechanical supports.
W243	the reason for each support,	
W244	the situations in which each is to be applied,	
W245	and a schedule for the use of each support.	
W246	(v) Provide that clients who have multiple disabling conditions spend a major portion of each waking day out of bed and outside the bedroom area, moving about by various methods and devices whenever possible.	§483.440(c)(6)(v) FACILITY PRACTICES: Individuals with sensory or physical difficulties have the same opportunities to move around in their environments as individuals who do not have those difficulties. v483.440(c)(6)(v) GUIDELINES: With the exception of those individuals who are acutely ill (such as those who are hospitalized or incapacitated by a short term illness), all individuals should be out of bed and outside their bedroom area as long as possible each day, and in proper body alignment at all times. This is a necessity in order to prevent regression, contractures, and deformities and to provide sensory stimulation. Question patterns of bed rest "orders" or "scheduled" bed rest as a routine part of an individual's program. A nap period of an hour, for example, is not "bed rest." However, if the ICF/MR, as a general pattern of scheduling, expects an individual to be one-two hours in bed in the morning, one-two hours in bed in the afternoon, and an 8:00 p.m. bedtime in the evening, for example, then the practice becomes "bed rest," and the intent of the regulation will more than likely not be met. Question seriously large amounts of time during which a resident is confined to bed. §483.440(c)(6)(v) PROBES: For those for whom out-of-bed activity is a threat to their health and safety, look for: o Individuals and staff engaged in activities to increase sensory stimulation; and o Equipment designed to promote increasing the individual's sensory stimulation. Is equipment available to provide access to community activities? Are mobility devices available and used as needed by individuals?

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W247	(vi) Include opportunities for client choice and self-management.	§483.440(c)(6)(vi) FACILITY PRACTICES: Individuals are provided opportunities for choice, encouraged and taught to make choices, and to exercise control over themselves and their environment. §483.440(c)(6)(vi) GUIDELINES: Due to the basic underlying importance "choice" plays in the quality of one's life, the ICF/MR should maximize daily activities for its individuals in such a way that varying degrees of decision-making can be practiced as skills are acquired. Examples of some activities leading toward responsibility for one's own self-management include, but are not limited to, choosing housing or roommates, choosing clothing to purchase or wear, choosing what to eat, making and keeping appointments, and choosing from an array of appropriate activities. Interview staff to determine how attitudes and activities of the team and consultants facilitate or impede individual choice. Choices can be made by all individuals. The type of choices the person makes may vary from very simple to more complex, depending upon individual abilities. Look at choices in the context of the individuals served by the facility.
W248	(7) A copy of each client's individual plan must be made available to all relevant staff, including staff of other agencies who work with the client, and to the client, parents (if the client is a minor) or legal guardian.	§483.440(c)(7) FACILITY PRACTICES: The individual or legal representative, as well as the facility staff, and staff from outside agencies have, or can access, a copy of the plan.
	(d) Standard: Program implementation.	
W249	(1) As soon as the interdisciplinary team has formulated a client's individual program plan, each client must receive a continuous active treatment program consisting of needed interventions and services in sufficient number and frequency to support the achievement of the objectives identified in the individual program plan.	§483.440(d)(1) FACILITY PRACTICES: Each individual is receiving training and services consistent with the current IPP. Staff use the adaptive equipment, assistive devices, environmental supports, materials, supplies, etc., specified in each individual's IPP to accomplish stated objectives. A consistent approach is being implemented in all environments. The pattern of interactions observed supports the active treatment program (e.g., informal opportunities to reinforce learning or appropriate skill development are taken, needs are addressed as they present themselves). The active treatment program is not delayed or suspended while waiting for the written IPP document. Activities support the accomplishment of the IPP objectives.

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		An individual's persistent refusal to participate in active treatment is being addressed by the IDT. §483.440(d)(1) GUIDELINES: For an individual newly admitted to the ICF/MR, the time period between admission and the 30 day interdisciplinary team meeting should be primarily for purposes of assisting the individual to become adjusted and acclimated to his or her new living environment and completing the functional assessment. During this time period the facility should also be providing those services and activities determined during the pre-admission assessment as essential to the individual's daily functioning. In order to be able to produce the comprehensive assessment, the facility must evaluate the individual's status in as many naturally occurring, functional environments as possible. It must be clear that the active treatment program received by the individual is internally consistent and not simply a series of disconnected formal intervention applications within certain scheduled intervals. The criteria of what constitutes a "sufficient number and frequency of interventions" are based on the individual's assessment and the progress the individual makes toward achieving IPP objectives. Whether "structure" must be imposed by staff or whether the individual can direct his or her own activities for a period of time (without direct staff observation) is based on the individual's ability to engage in constructive, age-appropriate, adaptive behavior (without engaging in maladaptive behavior to self or others). Be certain that an individual's time in the home or living unit is maximized toward the further development and refinement (including self-initiation) of appropriate skills, including, but not limited to, leisure and recreation. For the active treatment process to be effective, the overall pattern of interaction between staff and individuals must be accountable to the comprehensive functional assessment and the IPP process. During the overall observation of individuals, you should be able to track that: the individual's comprehensive assessment identified the specific developmental need or strength justifying the activity, technique or interaction; in the case of a "need," the team projected a measurable objective or target to address it; and the technique, interaction, or activity which is observed, produced the desired target, produced a close approximation of the target, or was modified based on the individual's response. §483.440(d)(1) PROBES: Does the activity schedule and the content of the activities relate directly to the strengths, needs and objectives in the IPP for each individual or are the activities/content "make work," generalized, non-developmental time fillers? Can staff describe how activities relate to strengths, needs and IPP objectives?

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		Are active treatment activities integrated into a "normal daily rhythm"? Are individuals observed performing scheduled active treatment activities? Are there sufficient and appropriate staff to implement IPPs? Is training on priority objectives implemented at discrete time intervals exclusively, or is training implemented as the individual's needs emerge during the course of the day, as well? Is there a consistent discernible pattern of evidence that staff implement, practice, reinforce, and otherwise carry out strategies to achieve individual objectives? At any point in time are IPP interventions observable during staff and individual interactions, in formal and informal settings alike, throughout the individual's living experience? Does the classroom, therapy or activity environment lend itself to the learning experience or are distractions, noise levels, or other individual behaviors obstacles to individual learning?
W250	(2) The facility must develop an active treatment schedule that outlines the current active treatment program and that is readily available for review by relevant staff.	§483.440(d)(2) FACILITY PRACTICES: The schedule is individualized and consistent with the individual's objectives. The schedule is known to staff working with the individual. Staff know where to locate a schedule when they need it. The active treatment schedule allows flexibility and is adjusted to the needs and preferences of the individual, as necessary. The active treatment schedule reflects normal daily rhythms. §483.440(d)(2) GUIDELINES: The active treatment schedule directs the intensity of the daily work of the staff and the individuals in implementation of the IPP in both informal and formal training activities. To the extent possible, the schedule provides a range of options, rather than a fixed regimen. Individuals should have opportunities to choose activities and to engage in them as independently and freely as possible. Staff routines and schedules should be supportive of this goal and result in the presence of reasonable choices by individuals. Investigate any pattern of staff action or scheduling which results routinely in all or the majority of individuals engaging in the same activity or routine at the same time. For example, everyone is out of bed, awake and dressed before staff on the third shift go home, or everyone goes to bed before the third shift arrives.

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		The active treatment schedule is not required to be posted. While the facility should have the individual's schedule from the day program, there is no requirement that this schedule and the residential schedule be merged into one document.
W251	(3) Except for those facets of the individual program plan that must be implemented only by licensed personnel, each client's individual program plan must be implemented by all staff who work with the client, including professional, paraprofessional and nonprofessional staff.	§483.440(d)(3) FACILITY PRACTICES: All staff working with the individual implement all aspects of the active treatment program unless such implementation is restricted to licensed personnel. Each discipline works together to provide a uniform, consistent approach to implementation of the IPP across disciplines. §483.440(d)(3) GUIDELINES: The facility is responsible for ensuring that during staff time spent with individuals, the staff member is able to provide needed interventions or reinforce acquired skills in accordance with the IPP. This is one of the ways the ICF/MR implements continuous active treatment. "All" staff includes direct care staff. The activities of the ICF/MR are coordinated with other habilitative and training activities in which the individual may participate outside of the ICF/MR, and vice versa. §483.440(d)(3) PROBES: Do staff assigned to work with the individual encourage him or her to perform activities of daily living with maximum independence? Is development and reinforcement of these skills implemented regularly? Is there evidence that each discipline working with the individual integrates, as appropriate, other disciplines' objectives and techniques? (For example, does direct care staff implement manual communications systems? Does the O.T. implement behavior management programs, if needed by the individual, during O.T. training sessions?) Are informal daily activities designed to promote choice, self-management, skill enhancement or reinforcement?
	(e) Standard: Program documentation.	
W252	(1) Data relative to accomplishment of the criteria specified in client individual program plan objectives must be documented in measurable terms.	§483.440(e)(1) FACILITY PRACTICES: Data are collected in the form and frequency required by the plan. Data are accurate, i.e., reflective of actual individual performance. §483.440(e)(1) GUIDELINES: Data collection is evidence of individual performance and should not be taken

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		constantly as evidence for surveyors that "treatments" occurred. "Data" are defined to be performance information collected and reported in numerical or quantifiable form on training objectives assigned priority in the IPP. Data are those performance measurements recorded at the time the treatment, procedure, intervention or interaction occurs with the individual. They should be located in a place accessible to staff who conduct training. §483.440(e)(1) PROBES: Do the data collected on an individual basis vary according to the nature of the task, or are data collected the same way for all individuals on all tasks? Do the data collected yield information relevant to making program decisions? Are the data collected on objectives implemented outside the agency also reviewed and analyzed to justify change in the objectives? Is there a correlation between recorded data and observed individual performance?
	(2) The facility must document significant events that	§483.440(e)(2) GUIDELINES: See also '483.410(c) Client Records.
W253	are related to the client's individual program plan and assessments and	§483.440(e)(2) FACILITY PRACTICES: Changes in the individual's functional status, health condition, accomplishments, activities or needs which affect the CFA and IPP are documented. §483.440(e)(2) PROBES: Is there a discernable pattern indicating that the facility routinely fails to detect the need to change individual programs? Does the facility record unusual episodes and other incidents that suggest the staff needs to respond with a changing program or other special attention?
W254	that contribute to an overall understanding of the client's ongoing level and quality of functioning.	§483.440(e)(2) FACILITY PRACTICES: Any occurrence(s) inside or outside the facility which provides information about the individual's interactions, responses, progress, or problems beyond the specific parameters of the IPP, are documented.
	(f) Standard: Program monitoring and change.	

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	(1) The individual program plan must be reviewed at least by the qualified mental retardation professional and revised as necessary, including, but not limited to situations in which the client- -	§483.440(f)(1)(i)-(iv) FACILITY PRACTICES: The QMRP ensures the program has been modified or changed in response to the individual's specific accomplishments, need for new programs, or difficulties in acquiring or maintaining skills. §483.440(f)(1)(i)--(iv) GUIDELINES: The interval within which IPP reviews are conducted is determined by the facility. However, the facility's review system must be sufficiently responsive to ensure that the IPP is reviewed whenever the conditions specified in "483.440(f)(1)(i-iv) occur. Information relevant to IPP changes should be recorded as changes occur. §483.440(f)(1)(i)--(iv) PROBES: Is the QMRP actually monitoring individual programs, or does the QMRP simply review paperwork? See also W159. Are timely modifications of unsuccessful programs or development of programs for unaddressed, but significant needs made or ensured by the QMRP? Does the QMRP routinely visit program areas and discuss performance and problems of individuals? Is there evidence that collected data are systematically recorded, analyzed, and used to make changes in programs? Can the QMRP describe the programs implemented with individuals for whom they are responsible or do they need to go to the record for this information?
W255	(i) Has successfully completed an objective or objectives identified in the individual program plan;	
W256	(ii) Is regressing or losing skills already gained;	
W257	(iii) Is failing to progress toward identified objectives after reasonable efforts have been made or;	
W258	(iv) Is being considered for training towards new objectives.	
	(2) At least annually,	§483.440(f)(2) GUIDELINES: For the "annual" review to meet the requirement, it must be completed by at least the 365th day after the last review. The ICF/MR may be required to conduct reviews at more frequent intervals by other, more stringent regulations (e.g., 90 day reviews required by '456.380(6)(c), State regulation, etc.). The facility's failure to comply with these other, more stringent regulations would NOT be cited under this requirement. Refer cases of suspected non-compliance to the authority having jurisdiction for the regulations in question.
W259	the comprehensive functional assessment of each client must be reviewed by the interdisciplinary team for relevancy and updated as needed;	§483.440(f)(2) FACILITY PRACTICES: The comprehensive functional assessment (CFA) is reviewed at least within the required timeframe. The review of the CFA occurs sooner than annually when indicated by the needs of the individual. The CFA reflects changes in the individual since the last assessment.

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		The CFA incorporates information about individual's progress, regression, etc. §483.440(f)(2) GUIDELINES: The review of the CFA applies to all evaluations conducted for an individual, unless otherwise specified in the regulation (e.g., annual physical examination). It is not required that each assessment be completely redone each year. It is required that at least annually the assessment(s) be updated when changes occur so as to accurately reflect the individual's current status. Systematic behaviorally stated data become part of the comprehensive functional evaluation of the individual.
W260	and the individual program plan must be revised, as appropriate, repeating the process set forth in paragraph (c) of this section.	§483.440(f)(2) FACILITY PRACTICES: The IPP reflects and responds to functional changes which have occurred since the last IPP. §483.440(f)(2) GUIDELINES: Look for IPPs that are unchanged from one year to the next, for priority skills and behaviors that are deferred or ignored for one reason or the other, and for informal, vague, and programmatically worthless statements in the review (such as "John did better this year--he wasn't as upset most of the time like he used to be). If the ICF/MR has not been providing the individual with a systematic, behaviorally-oriented active treatment program during the year, the review will be incapable of making systematic, behaviorally-oriented statements about progress and change. If you find problem behaviors which do not decrease significantly, relatively frequent usage of restraint or other intrusive restrictive procedures, a "plateauing" (e.g., reaches partial desired performance, but does not improve over time and staff does not reassess) of skills development, or any other signs of "sameness" year after year, questions should be raised about the extent to which the ICF/MR is providing active treatment, the adequacy of IPPs, staff training, etc., particularly, if many individuals' annual reviews reveal these characteristics. §483.440(f)(2) PROBES: Does the annual review result in actual changes in the individual's programs, or is it a "rubber stamp" duplication of the prior year's plan? Does the facility respond routinely to the need for change in an individual's program or does an individual's program tend to be changed only once a year or on a time periodic basis (e.g., every quarter or six months)? Is there a logical relationship among goals and objectives from year to year or are objectives established in a fragmented, unrelated pattern from year to year? Can the reason for changes, deletions, or additions to IPP objectives be identified?

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W261	(3) The facility must designate and use a specially constituted committee or committees consisting of members of facility staff, parents, legal guardians, clients (as appropriate), qualified persons who have either experience or training in contemporary practices to change inappropriate client behavior, and persons with no ownership or controlling interest in the facility to--	'§83.440(f)(3) FACILITY PRACTICES: The facility has a specially constituted committee. The committee is used to accomplish the requirements of W262, W263 and W264. The committee has the required membership and those members participate regularly in the functioning of the committee. §483.440(f)(3) GUIDELINES: Depending on its size, complexity and available resources, the ICF/MR may establish one multi-purpose committee to serve it for all advisory functions, or it may establish separate single-purpose committees. The facility's human rights committee may be shared among other agencies or the ICF/MR may utilize a human rights committee established by another governing body, e.g., a county or a statewide group, as long as all pertinent regulatory requirements are met. The regulation does not specify the professional credentials of the "qualified persons who have either experience or training in contemporary practices to change inappropriate client behavior". There is no requirement that any specific disciplines, such as nurse, physician or pharmacist be members of the committee. The intent of including "persons with no ownership or controlling interest" on the committee is to assure that, in addition to having no financial interest in the facility, at least one member is an impartial outsider in that he/she would not have an "interest" represented by any other of the required members or the facility itself. Staff and consultants employed by the facility or at another facility under the same governing body cannot fulfill this role. Although occasional absences from committee meetings are understandable, patterns of absence by the required membership of the committee is not acceptable. At least a quorum of committee members must review, approve and monitor the programs which involve risk to client rights and protections. Depending upon the size of the facility and the number of individuals who need intrusive or restrictive techniques as a part of active treatment programs, more than one specially constituted committee may be needed to effectively meet the intent of the regulation. The facility is responsible to organize itself in a manner which permits the timely review of proposed programs.
W262	(i) Review, approve, and monitor individual programs designed to manage inappropriate behavior and other programs that, in the opinion of the committee, involve risks to client protection and rights;	§483.440(f)(3)(i) FACILITY PRACTICES: Any programs which incorporate restrictive techniques (e.g., restraints, medication to manage behavior, restrictions on community access, etc.) have been reviewed and approved by the committee prior to implementation. The committee periodically monitors restrictive programs to determine if the restriction of rights or risk to protections remains justified.

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		§483.440(f)(3)(i) GUIDELINES: Each individual program developed to decrease inappropriate behavior and which involves potential risk to rights and protections must be reviewed and approved by the committee prior to the program's implementation. Some examples of programs requiring review include, but are not limited to, programs incorporating usage of restraints, aversive conditioning, any medication used to modify behavior, contingent denial of any right or "earning" of a right as part of a behavior shaping strategy, and behavioral consequences involving issues of client dignity. There is no requirement for the committee to function as a peer review for technical or clinical adequacy of plans submitted for approval. The purpose is to assure that each individual's rights are protected through use of a group of outside individuals who are not invested in the maintenance of facility practices. The committee reviews the context by which each program is recommended, and then evaluates whether the program's level of intrusiveness is warranted. The committee should consider factors such as whether less intrusive methods have been attempted and whether the severity of behavior outweighs the risks of the proposed program. The committee need not reapprove a program when revisions are made, as long as those revisions are in accordance with the approved plan. For example, if the physician changes the dosage of a medication in accordance with the drug treatment component of the active treatment plan to which the legally authorized person has given consent and which has already been approved by the committee, then there is no need for the committee or the legally authorized person to reapprove the plan. (See also W263.) Generally, this would also apply if the medication was changed to another within the same therapeutic class or family. Reapproval would be needed, however, if the reason for the change was the individual's strong untoward response to the original medication. Due to the differences in side effects and potential adverse response between drugs of a different class, reapproval would also be required if the new medication was from a different therapeutic class or family of drugs. §483.440(f)(3)(i) PROBES: Does the committee generally approve whatever staff recommends without substantive review? Does the committee require that less restrictive means be demonstrated to be ineffective? What is the length of time from program submission to committee review? Do you discern a pattern of committee involvement in the ongoing monitoring of approved programs? Does the committee seek changes, if indicated? If staff assigned to the committee(s) are also members of the particular individual's interdisciplinary team, does that staff member abstain from approving formally the individual's program?

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W263	(ii) Insure that these programs are conducted only with the written informed consent of the client, parents (if the client is a minor) or legal guardian; and	§483.440(f)(3)(ii) FACILITY PRACTICES: Written consent is present prior to implementation of any restrictive program. Consent is given by the legally appropriate party. The consent is for the program which incorporates the use of a restrictive technique, rather than the restrictive technique alone. The consent is informed, i.e., the person giving consent is aware of the risks, benefits, alternatives, right to refuse and consequences. §483.440(f)(3)(ii) GUIDELINES: Informed consent consists of permission by the legally responsible party after having been informed of the specific issue, treatment or procedure; the individual's specific status with regard to the issue, treatment or procedure; the attendant risks and benefits; alternative forms of treatment; the right to refuse treatment and the consequences of that refusal. Informed consent implies that the person who is to give consent is competent to evaluate the decision requiring consent. For children up to the age of 18 the parent (natural guardian) or legally appointed guardian must give consent for him or her. At the age of 18, however, children become adults and are assumed to be competent unless otherwise determined by a court. For individuals who are minors or who are clearly incompetent, but have no appointed legal guardian, informed consent for use of restrictive programs, practices or procedures must be obtained from the legal guardian, parent or someone or some agency designated by the State, in accordance with State law, to act as the representative of the individual's interests. Become familiar with the statutes of the State in which the ICF/MR is located to determine who or what mechanism is designated to give informed consent in such circumstances. Verify whether or not consent was obtained in accordance with law. Additionally, under these circumstances, the facility is required to identify those individuals, and expected to advocate for them by demonstrating continuing efforts to obtain timely adjudication of the individual's legal status. The committee must ensure that the informed and voluntary consent of the individual, parent of a minor, legal guardian, or the person or organization designated by the State is obtained prior to each of the following circumstances: the involvement of the individual in research activities, or implementation of programs or practices that could abridge or involve risks to individual protections or rights. Informed consent should be specific, separate ("blanket" consents are not allowed), and in writing. In case of unplanned events requiring immediate action, verbal consent may be obtained, however, it should be authenticated in writing as soon as reasonably possible.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
W264	(iii) Review, monitor and make suggestions to the facility about its practices and programs as	§483.440(f)(3)(iii) FACILITY PRACTICES: The committee has been made aware of and reviewed facility programs and practices which may affect the rights of individuals.

	they relate to drug usage, physical restraints, time-out rooms, application of painful or noxious stimuli, control of inappropriate behavior, protection of client rights and funds, and any other areas that the committee believes need to be addressed.	Committee recommendations have been addressed by the facility. The committee has established and uses a mechanism for monitoring individuals' rights issues. §483.440(f)(3)(iii) GUIDELINES: The function of the committee is not limited to the review, approval and monitoring of restrictive behavior management practices. Examples of individual rights issues that might be reviewed by the committee, in addition to behavior management, include, but are not limited to, research proposals involving individuals, abuse, neglect and mistreatment of individuals, allegations dealing with theft of an individual's personal property or funds, damage to an individual's goods or denial of other individual rights, individual grievances, visitation procedures, guardianship/advocacy issues, rights training programs, confidentiality issues, advance directives/DNR orders, etc.
W265	(4) The provisions of paragraph (f)(3) of this section may be modified only if, in the judgment of the State survey agency, Court decrees, State law or regulations provide for equivalent client protection and consultation.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
W266	§483.450 Condition of participation: Client behavior and facility practices.	§483.450 COMPLIANCE PRINCIPLES: The Condition of Participation of Client Behavior and Facility Practices is met when: o Individual programs and activities regularly include use of positive techniques, teaching strategies, and supports. Efforts are made to reduce and eliminate use of restrictive techniques with positive results; o Staff teach and reinforce appropriate behaviors, such as communication skills, social skills, independence and choice-making skills, coping skills, and leisure skills which serve as functional substitutes for inappropriate behaviors; and o Restrictive techniques are used only when warranted by the severity of the behavior, and result in desired behavioral outcomes. The Condition of Participation of Client Behavior and Facility Practices is not met when: o Restrictive, intrusive techniques are used to manage or control behavior in lieu of positive teaching strategies; o Individuals are physically or psychologically injured or harmed as a result of the use of the restrictive interventions and the facility has failed to adequately monitor the use of the intervention; or o Restrictive interventions are used when they are not warranted or without first attempting less restrictive/more positive measures.
	(a) Standard: Facility practices--Conduct toward clients.	
W267	(1) The facility must develop and implement written policies and procedures for the management of conduct between staff and clients.	§483.450(a)(1) FACILITY PRACTICES: Observed practices regarding the behavior and interactions of staff and individuals served demonstrate proactive assertion of the individual's right to learn to exercise his or her rights. §483.450(a)(1) GUIDELINES: "Conduct between staff and clients" refers to the language, actions, discipline, rules, order, and other types of interactions exchanged between staff and individuals or imposed upon individuals by staff during an individual's daily experiences and which affect the quality of an individual's life. While the regulation requires the development of written policies and procedures, the primary survey emphasis should be placed on the latter aspect of the regulation, i.e., implementation of those policies and procedures. Observations of interactions between staff and individuals should confirm that, to the maximum extent possible, individuals are provided with opportunities for growth and self-determination. Individual's dignity is respected by staff and their behavior is within the context of any rules of conduct which have been established.
	These policies and procedures must- -	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
W268	(i) Promote the growth, development and independence of the client;	§483.450(a)(1)(I) FACILITY PRACTICES: Staff are observed engaged in activities which promote the individual's growth, development and independence. Individual program plans and data support the fact that from the time of admission, individuals are learning new adaptive and functional skills while becoming more independent. There are consistent positive interactions between individuals and staff. Staff teach and encourage individuals to interact with each other in a socially acceptable manner. Opportunities to teach and reinforce skill acquisition are utilized. Staff identify and remove impediments in the learning environment. Staff encourage individuals to complete tasks with as much independence as possible. Staff encourage individuals to take risks while providing reasonable safeguards to prevent injury.
W269	(ii) Address the extent to which client choice will be accommodated in daily decision-making, emphasizing self-determination and self-management, to the extent possible;	§483.450(a)(1)(I) FACILITY PRACTICES: Staff actively engage in practices which provide individuals with opportunities for choice, decision-making and self-management, promote participation in these opportunities and provide necessary supports as the individual becomes more independent. Appropriate and purposeful activities and materials known to be preferred by the individual are available. Alternatives are available for individuals who do not choose to participate in a planned activity. Individual's preferences and choices play a key role in daily decision-making.
W270	(iii) Specify client conduct to be allowed or not allowed; and	§483.450(a)(1)(iii) FACILITY PRACTICES: Individuals know the benefits and consequences of their conduct or behavior. Staff are aware of what is or is not permissible and the positive or negative consequences which may be utilized. Staff behavior is consistent with this policy. §483.450(a)(1)(iii) GUIDELINES: "Client conduct" refers to any behavior, choice, action, or activity in which an individual may choose to engage alone or with others.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		The policy or "house rules" include(s), for example: allowable individual conduct (e.g., swearing or cursing, freedom of choice in religion, consumption of alcohol, smoking, sexual relations), reasonable locations where this conduct may or may not occur, and parameters for decision-making when an individual's choice conflicts with the group's choice (e.g., consensus, voting, taking turns, negotiation of differences). "House rules" on the other hand, may not authorize staff or other individuals served to use a "laundry list" of discipline techniques to control an individual's inappropriate behavior, without regard to individualized need. If it is determined that staff must use a technique or intervention, then its use must be incorporated into an individual program plan that meets all applicable requirements specified in §483.450(b)-(e). Refer to W5123.
W271	(iv) Be available to all staff, clients, parents of minor children, and legal guardians.	
W272	(2) To the extent possible, clients must participate in the formulation of these policies and procedures.	§483.450(a)(2) FACILITY PRACTICES: Input and participation of the individuals residing in the facility has been obtained in developing/revising the policies and procedures.
W273	(3) Clients must not discipline other clients, except as part of an organized system of self-government, as set forth in facility policy.	
	(b)Standard: Management of inappropriate client behavior.	
W274	(1) The facility must develop and implement written policies and procedures that govern the management of inappropriate client behavior.	§483.450(b)(1) FACILITY PRACTICES: Programs and practices used to manage behaviors are consistent with written policies and procedures. §483.450(b)(1) GUIDELINES: Use of items, procedures, or systems which are potentially stigmatizing to the individual or otherwise would represent a substantial departure from the behavior of comparable peers without disabilities, to control or prevent inappropriate behavior, falls under this requirement as well. (For example, requiring an individual to live in a locked residence and not providing the individual with a key, using a high crib with bedrails for an adult who gets out of bed at night and wanders or upsets other individuals, requiring an individual who strips off his clothes at inappropriate times to wear a jumpsuit turned backwards, or other odd usages of fashion.)
	These policies and procedures must be	
W275	consistent with the provisions of paragraph (a) of this section.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	These procedures must- -	
W276	(i) Specify all facility approved interventions to manage inappropriate client behavior;	§483.450(b)(1)(i) FACILITY PRACTICES: All positive as well as intrusive behavioral interventions approved for use in the facility are clearly stated in its policy.
W277	(ii) Designate these interventions on a hierarchy to be implemented, ranging from most positive or least intrusive, to least positive or most intrusive;	§483.450((b)(1)(ii) FACILITY PRACTICES: There is a clear progression in how techniques are implemented from the most positive, functionally appropriate approaches to most intrusive approaches authorized.
W278	(iii) Insure prior to the use of more restrictive techniques, that the client's record documents that programs incorporating the use of less intrusive or more positive techniques have been tried systematically and demonstrated to be ineffective; and	§483.450(b)(1)(iii) FACILITY PRACTICES: In emergency situations where an unanticipated behavior requires immediate protection of the individual or others, the technique chosen is the least restrictive clinically appropriate technique possible. Based on a functional analysis of the behavior and the data resulting from use of positive/less restrictive techniques, there is clinically sound, professionally accepted justification before the implementation of any more restrictive techniques. §483.450(b)(1)(iii) GUIDELINES: You should see clear evidence to justify the use of a more restrictive technique. This requirement does not take away the team's discretion to use technology which represents reasonable standards of good practice, but it does require that there be evidence that justifies any decision not to use a positive or less restrictive technique first. Based on extraordinary circumstances resulting in an emergency, a facility may need to use a more restrictive method of intervention to protect the individual and others from harm than is consistent with the hierarchy it has established. This regulation does not prohibit a facility from using good judgement in this situation. The surveyor should assess the use of emergency restrictive interventions to assure that the facility could not have reasonably anticipated the behavior, and verify that the team has reviewed the individual program plan for its adequate attention to the problem precipitating the emergency measure. The facility is not required to justify discontinuing the use of a more restrictive technique before initiating a less restrictive technique, since the intent of the regulation is to use the most positive, least intrusive technique possible. §483.450(b)(1)(iii) PROBES: Do individuals observed with behavior problems (e.g., aggression, withdrawal, stereotypical, self-abusive) have individually designed behavior programs? Does the "maladaptive" behavior ever occur as an "appropriate" response given the individual's circumstances?

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		How has the staff tried to determine what the individual is trying to accomplish or communicate by displaying the maladaptive behavior? How do they respond to the behavior and the need being communicated? Was the possibility addressed that the inappropriate behaviors might be an expression of a mental disorder? Was a medical and/or psychiatric consultation obtained, especially if a treatment program was unsuccessful for a reasonable length of time? Are there consistent positive reinforcement procedures used with individuals? What specific individual behaviors do staff report they are to reinforce or are observed to be reinforcing? Would environmental alterations alone reduce or eliminate the maladaptive behavior? Does the team consider attempting environmental changes before instituting a more restrictive program to control inappropriate behavior? Is there evidence of interventions to change the conditions which lead to inappropriate behavior?
	(iv) Address the following:	
W279	(A) The use of time-out rooms;	§483.450(b)(1)(iv) GUIDELINES: "Time-out rooms" is defined as the use of a room to implement a clinical procedure by which an individual is removed from positive reinforcement contingent upon the exhibition of a maladaptive behavior, until appropriate or adaptive behavior is exhibited. See also §483.450(c).
W280	(B) The use of physical restraints;	"Physical restraint" is defined as any manual method or physical or mechanical device that the individual cannot remove easily, and which restricts the free movement of, normal functioning of, or normal access to a portion or portions of an individual's body. Examples of manual methods include therapeutic or basket holds and prone or supine containment. Examples of mechanical devices include arm splints, posey mittens, helmets, and straight jackets. Excluded are physical guidance and prompting techniques of brief duration and mechanical supports as defined in §483.440(c)(6)(iv) GUIDELINES to position or support an individual. See also §483.450(d).
W281	(C) The use of drugs to manage inappropriate behavior;	"Drugs to manage inappropriate behavior" is defined as medications prescribed and administered for purposes of modifying the maladaptive behavior of an individual. See also §483.450(e).

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W282	(D) The application of painful or noxious stimuli;	"Application of painful or noxious stimuli" is defined as a clinical procedure by which staff apply, contingent upon the exhibition of maladaptive behavior, startling, unpleasant, or painful stimuli, or stimuli that have a potentially noxious effect. The application of painful or noxious stimuli is used as a last resort and only when documentation shows that implementation of consistent positive reinforcement methods have failed and that to withhold the procedure would cause irreparable harm to the health of the individual or others. Discomfort to the individual should not extend beyond the point of application of the stimuli. There must be continuous monitoring while the procedure is in effect. The procedure must not result in physical or mental harm to the health and safety of the individual.
W283	(E) The staff members who may authorize the use of specified interventions;	
W284	(F) A mechanism for monitoring and controlling the use of interventions.	As interventions become more restrictive, the specificity with which they must be explained increases, as does the intensity of the control established by the facility. This includes other techniques having similar degrees of intrusiveness to those defined above, such as positive practice and overcorrection training of extended duration and satiation.
W285	(2) Interventions to manage inappropriate client behavior must be employed with sufficient safeguards and supervision to ensure that the safety, welfare and civil and human rights of clients are adequately protected.	§483.450((b)(2) FACILITY PRACTICES: Monitoring has insured that individual rights are protected. Monitoring which is appropriate to the type of intervention being used, is in place to assure that the individual does not suffer unfavorable effects from the intervention. §483.450(b)(2) PROBES: What mechanism does the facility use to ensure that approval does not extend longer than warranted? To what extent is the special review committee involved in monitoring? Do the procedures deny requisite human needs, such as sleep, shelter, bedding, or use of bathroom facilities? Are rights denied in the absence of the required consent and approvals? Are drugs used to manage inappropriate behavior monitored for unfavorable side effects?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(3) Techniques to manage inappropriate client behavior must never be used	
W286	for disciplinary purposes,	§483.450(b)(3) FACILITY PRACTICES: No technique, whether a part of a formal program or in informal situations, is used as retaliation or retribution. §483.450(b)(3) PROBES: How commonly are these techniques used? What types of problems are they used for? Do these techniques continue to be implemented and/or authorized regardless of individual success on individual program plan objectives? Are restraints, time-out rooms or drugs used for environmental deficiencies (e.g., lack of staff, program structure)?
W287	for the convenience of staff	§483.450(b)(3) FACILITY PRACTICES: No technique, whether a part of a formal program or in informal situations, is used to compensate for lack of staff presence or competency. §483.450(b)(3) PROBES: Are the behaviors listed as problematic occurring only in certain situations, such as in living areas and on weekends, possibly indicative of understaffing? Are the problematic behaviors occurring during day programs, possibly indicative of inappropriate placement? Is there a systematic pattern showing restrictive technique usage occurring more frequently in units where staffing is not optimal? Where there is frequent staff turnover? Is usage tied directly to a carefully approved behavior reduction program? Or, is it in practice, a means of locking individuals at the convenience of staff or in the absence of effective programming?
W288	or as a substitute for an active treatment program.	§483.450(b)(3) FACILITY PRACTICES: Any intervention used is tied to a specific active treatment program which addresses both the inappropriate behavior and mechanisms to teach, improve, support, or substitute appropriate behaviors. §483.450(b)(3) PROBES: Does the program to control inappropriate behavior actually address the problems identified, or is it, in fact, a behavior control/punishment program that does not result in desired behavior outcomes?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
W289	(4) The use of systematic interventions to manage inappropriate client behavior must be incorporated into the client's individual program plan, in accordance with §483.440(c)(4) and (5) of this subpart.	§483.450(b)(4) FACILITY PRACTICES: All behavior interventions/supports are part of the individual program plan. All interventions are written as rigorously as other individual program plan training objectives and, in addition, include the extra provisions required by tags W238 and W239. §483.450(b)(4) PROBES: Are behavior programs demonstrably implemented in formal and informal settings alike as per the individual program plan? Is there a complete description of the behavior occurring and evidence to show that as inappropriate behaviors diminish, desired, appropriate behaviors increase?? Does the facility change the program as individual behavior indicates? What specific appropriate behaviors are being taught, improved, supported or substituted for the maladaptive behavior?
W290	(5) Standing or as needed programs to control inappropriate behavior are not permitted.	§483.450(b)(5) FACILITY PRACTICES: All interventions addressing the control of inappropriate behaviors are justified by the functional assessment and the current level of behavior. §483.450(b)(5) GUIDELINES: Ongoing authorization for "programs" or "programmatic usages" of restrictive techniques, in the absence of evidence to justify such usage, constitutes a "standing" or "as needed program" to control inappropriate behavior, and are therefore not permitted. §483.450(b)(5) PROBES: Is there a pattern of restrictive techniques used in tandem (e.g., an individual is released from time-out but is then put in another type of restraining device)? Is there a long term pattern of usage without discernible gains in individual progress? Do individual records contain "approved" programs incorporating restrictive techniques, yet there is: o Only episodic frequency of the maladaptive behavior? o Relatively rare usage of the restrictive technique? o No previously tried and implemented positive strategies showing lack of success?
	(c) Standard: Time-out rooms.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
W291	(1) A client may be placed in a room from which egress is prevented only if the following conditions are met: (i) The placement is a part of an approved systematic time-out program as required by paragraph (b) of this section. (Thus, emergency placement of a client into a time-out room is not allowed.) (ii) The client is under the direct constant visual supervision of designated staff. (iii) The door to the room is held shut by staff or by a mechanism requiring constant physical pressure from a staff member to keep the mechanism engaged.	§483.450(c)(1) GUIDELINES: The use of time-out rooms is effective only if the individual does not like to be removed from an activity or from people. Look for patterns of frequent, lengthy time-out usage which often indicates that the environment is not reinforcing to the individual (i.e., the activities in and of themselves are not engaging, and/or the scheduled activities are potentially engaging yet the schedule is not implemented). If the individual who is in a time-out room engages in self-abuse, becomes incontinent or shows other signs of illness, staff should immediately discontinue the procedure and intervene. Verify whether or not anyone standing or lying in any position, in any part of the time-out room can be seen. Key locks, latch locks, and doors that open inward without an inside doorknob are not devices or mechanisms which require constant physical pressure from a staff member to keep a door shut, and, therefore, are not permitted by the regulations. Pressure sensitive mechanisms must allow staff to enter the room at the moment the need arises. §483.450(c)(1) PROBES: What reasons cause individuals to be placed in time-out rooms most frequently? Is there a pattern of time-out usage? What is it? On the average, how long are individuals placed in "time-out rooms"? Is time-out room usage extended on a routine basis? Does the frequency of time-out room usage indicate that isolation is more reinforcing to the individual than the environment? Are there plans to move to less restrictive means of modifying the behavior? Is criterion clearly specified for use/discontinuance of time-out rooms? What do staff do with individuals after they leave time-out rooms? Is usage directly tied to a carefully approved behavior reduction program or is it in practice a means of locking individuals at the convenience of staff or in the absence of effective programming? How do staff monitor individuals in time-out rooms? What do staff do if an individual in a time-out room screams? Engages in self-abuse? Becomes incontinent? Shows signs of medical illness?
W292	(2) Placement of a client in a time-out room must not exceed one hour.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
W293	(3) Clients placed in time-out rooms must be protected from hazardous conditions including, but not limited to, presence of sharp corners and objects, uncovered light fixtures, unprotected electrical outlets.	§483.450(c)(3) GUIDELINES: A door that opens inward can potentially be held closed, either intentionally or inadvertently, by the individual in the room, thereby denying staff immediate access to the room.
W294	(4) A record of time-out activities must be kept.	§483.450(c)(4) FACILITY PRACTICES: The record accurately reflects planned (i.e., part of the individual program plan) and emergency usage and presents a picture of events prior to, during, and following the use of time-out. §483.450(c)(4) PROBES: Can staff show how long and frequently time-out has been used? Can staff describe what environmental variables contributed to each time-out usage?
	(d)Standard: Physical restraints.	
	(1) The facility may employ physical restraint only- -	
W295	(i) As an integral part of an individual program plan that is intended to lead to less restrictive means of managing and eliminating the behavior for which the restraint is applied;	§483.450(d)(1)(i) FACILITY PRACTICES: The use of physical restraint is specified within the individual program plan. Physical restraint is used only in response to a specific type and/or severity of behavior and only for the amount of time specified in the individual program plan. The plan is directed toward reduction of the use of restraints. §483.450(d)(1)(i) PROBES: What is the reason for the restraint? Does the individual program plan identify the type of restraint to be used? Does the severity of the behavior justify its usage? Does the facility consider factors other than the individual in determining causes for need for restraints (e.g., other individuals, staff, building noise, sufficiency of program structure)? Are there clear, performance-based linkages between use of restraints in practice and behavior programs that use restraints? Or are restraints used in ways and at times other than prescribed in the individual's program?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
W296	(ii) As an emergency measure, but only if absolutely necessary to protect client or others from injury; or	§483.450(d)(1)(ii) FACILITY PRACTICES: Emergency physical restraint for an unanticipated type or severity of behavior is used only to prevent injury to the individual or others. §483.450(d)(1)(ii) GUIDELINES: "Emergency measure" is defined as use of the least restrictive procedures and for the briefest time necessary to control severely aggressive or destructive behaviors that place the individual or others in imminent danger when those behaviors reasonably could not have been anticipated, and only as they are necessary within the context of positive behavioral programming. Examine closely how frequently "emergency measures" are employed. Repeated applications of such measures within short intervals of time, without subsequent incorporation into a written active treatment program, as required by §483.440(c), raises serious questions about the individual's receipt of active treatment and the individual's right to be free from unnecessary restraint. §483.450(d)(1)(ii) PROBES: Is there a systematic pattern of incidents being called "emergencies" in order to apply restraints without use of an approved program? Are repeated emergency applications of restraints followed up with development of systematic behavior management programs? Is use of an emergency application documented and reviewed by the QMRP or designee with appropriate follow-up?
W297	(iii) As a health-related protection prescribed by a physician, but only if absolutely necessary during the conduct of a specific medical or surgical procedure, or only if absolutely necessary for client protection during the time that a medical condition exists.	§483.450(d)(1)(iii) FACILITY PRACTICES: Physical restraint is employed for medical reasons only when no other option is available or when no other option has proven effective in achieving the needed result for a particular individual, based on input from the IDT. In the presence of a restraint intended to be a health-related protection, there is an active medical condition at the time the physical restraint is used. §483.450(d)(1)(iii) PROBES: What do staff do to prepare individuals for medical or dental examinations in order to reduce the need for physical or mechanical restraints? Have other options such as desensitization training, behavior shaping, intensive positive reinforcement, environmental changes, etc. been tried? Are individuals routinely restrained before medical or dental examinations?
	(2) Authorizations to use or extend restraints as an emergency measure must be:	§483.450(d)(2) GUIDELINES: The facility determines who may authorize use of emergency restraints.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
W298	(i) In effect no longer than 12 consecutive hours; and	§483.450(d)(2)(i) GUIDELINES: The specific 12-hour authorization and re-authorization to use or extend usage of physical restraints does not apply to restraints used as an integral part of the individual program plan or to those that qualify as a health-related protection, as defined in the regulation.
W299	(ii) Obtained as soon as the client is restrained or stable.	§483.450(d)(2)(ii) GUIDELINES: This refers to the reporting and retrospective authorization of the emergency measure when no prior use authorization could be obtained due to the seriousness and immediacy of the event.
W300	(3) The facility must not issue orders for restraint on a standing or as needed basis.	
W301	(4) A client placed in restraint must be checked at least every 30 minutes by staff trained in the use of restraints,	§483.450(d)(4) GUIDELINES: The frequency of monitoring will vary according to the type and design of the device and the psychological and physical well-being of the individual. For example, an individual in four-point restraints might require constant monitoring while someone in soft mittens may require less frequent monitoring. It is also true that for some individuals, constant visual supervision would serve to reinforce the inappropriate behavior and thereby reduce the clinical effectiveness of using the restraint. However, in no case may the 30 minute time limit be extended. "As quickly as possible" means as soon as the individual is calm or no longer a danger to self or others. §483.450(d)(4) PROBES: Is there a pattern that individuals are placed in restraints repeatedly for 2-hour consecutive applications during the entire restraint authorization period? Does the team decide whether constant or frequent monitoring is helpful or contraindicated for an individual? On what basis is this decision made? When staff apply restraints do they demonstrate proper usage per each individual's program? Is the use of restraints well documented to present a clear picture of the events prior to, during, and following its use? Is this information reviewed by the IDT and addressed?
W302	released from the restraint as quickly as possible, and	
W303	a record of these checks and usage must be kept.	
	(5) Restraints must be designed and used	§483.450(d)(5) PROBES: Is there documentation in an individual's record regarding contraindications, if any, to certain types of restraints? How will the individual's safety be ensured?

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		How do staff decide which type of restraint to use for a particular individual?
W304	so as not to cause physical injury to the client	
W305	and so as to cause the least possible discomfort.	
	(6) Opportunity for motion and exercise must be provided	483.450(D)(6) GUIDELINES: "Motion and exercise" includes an opportunity for liquid intake and toileting, if needed by the individual.
W306	for a period of not less than 10 minutes during each two hour period in which restraint is employed,	§483.450(d)(6) GUIDELINES: In the presence of a restraint being worn during sleeping hours, surveyors must determine whether it is truly the nature of the individual's behavior which warrants this significant level of intrusion, or whether it in fact is a substitute for lower staffing during night time hours. The "motion and exercise" requirement applies to all restraints which restrict the range of motion of a limb or joint. Therefore, for example, if a helmet is applied to protect a head wound during sleeping hours, and the individual's range of motion in the neck has not been affected, then this requirement does not apply. This requirement also does not apply to cases of medical restraints that are specifically ordered for the immobilization of bones and joints during the physical healing process involved with fractures, sprains, etc. (e.g., a broken bone immobilized by a cast or splint). However, if a physical restraint was applied to an extremity to prevent an individual from removing post-operative sutures, the restraint would be required to be released every two hours for a period of not less than 10 minutes. Even though usage of mechanical supports, defined at §483.440(c)(6)(vi), may confine the movement of an individual, W306 does not apply to such usage.
W307	and a record of such activity must be kept.	
	(7) Barred enclosures	§483.450(d)(7) PROBES: For what reason does staff use barred enclosures? How long do individuals remain in these devices? What other interventions have been tried? Are use of these enclosures incorporated into individually designed plans, aimed at elimination of the behavior causing the need?
W308	must not be more than three feet in height and	
W309	must not have tops.	

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	(e) Standard: Drug usage.	
W310	(1) The facility must not use drugs in doses that interfere with the individual client's daily living activities.	§483.450(e)(1) FACILITY PRACTICES: Individuals who are receiving medications are alert and available for participation in daily living activities, unless a well-documented condition (e.g., significant seizure activity) warrants the use of medication in sedating quantities to adequately control that condition. §483.450(e)(1) GUIDELINES: §483.450(e)(1) applies to all medications, including medications prescribed to control inappropriate behavior. Overmedication occurs for many reasons. For medications prescribed to control maladaptive behavior, the most common reasons are: the individual's maladaptive behavior may not be responsive to drugs (e.g., if an individual has a non-drug-responsive form of self injury, then use of psychotropics may simply lead up to maximum drug doses without suppressing the behavior), drug therapy may be exacerbating the behavior (e.g., if a drug-induced side effect is mistaken for agitation, then the physician may mistakenly believe that the individual is undermedicated and increase the dose), presence of polypharmacy within the same drug class may result in a drug dose that would exceed the maximum daily limit for any one drug, the individual may be receiving too frequent injections which may result in significant drug accumulation over time, and the use of daily medication plus PRN or stat (one time) doses may result in greater than the recommended daily doses being prescribed (especially since intramuscular administration may be up to four times as potent). Overmedication may also occur as a result of the interaction between drugs, whether these drugs were prescribed for control of inappropriate behavior, or for a physical or medical condition. Administration of PRN or stat doses for periods greater than a few weeks may indicate that the individual's daily dose is sub-therapeutic, the problem will not respond to the prescribed drug or the drug is exacerbating the problem. In such instances, the surveyor should verify whether or not the drug regimen has been reassessed. §483.450(e)(1) PROBES: Are individuals who receive medications lethargic and inactive during the day? If so: O How long has the individual been on medication? O How long have the overt behaviors of lethargy and inactivity been noticed? O Have there been any attempts to taper the medication down? Is there evidence that the medication helps to facilitate the individual's participation in his/her individual program plan objectives?
	(2) Drugs used for control of inappropriate behavior must	

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W311	be approved by the interdisciplinary team and	§483.450(e)(2) FACILITY PRACTICES: The physician and other team members have discussed the risks and benefits of the medication to address the target behavior/symptoms, and has approved the use of the drug as being consistent with the active treatment program.
W312	be used only as an integral part of the client's individual program plan that is directed specifically towards the reduction of and eventual elimination of the behaviors for which the drugs are employed.	§483.450(e)(2) FACILITY PRACTICES: The individual program plan identifies the drug usage and how it may change in relation to progress or regression in the objective. The individual program plan contains specific criteria for any PRN usage. §483.450(e)(2) GUIDELINES: For drugs to be an effective therapeutic tool, they must be prescribed only to the extent that they are necessary for normal medical management of the individual. In an emergency, a physician may authorize the use of a drug to control an inappropriate behavior. However, orders for continued emergency drug usage cannot continue until the team gives approval and the drug's usage has been included in the plan. Psychotropic drug therapy may not be used outside of an active treatment program targeted to eliminate the specific behaviors which are thought to be drug responsive. Although only a physician can prescribe medication, the decision to use medication for control of behavior must be based on input from other team members. W329 and W330 address the physician's participation in the person's individual program plan as part of the interdisciplinary team. The interdisciplinary team involvement in this decision-making process is inextricably linked to an obligation to develop and implement effective non-drug interventions that address the targeted behavior. This obligation requires constant monitoring of the non-drug interventions to determine its efficacy, and to determine whether the judicious use of drug therapy may at times be appropriate. Individuals who receive psychoactive drugs for behaviors associated with a diagnosed mental disorder, require an active treatment program designed to reduce, ameliorate, compensate or eliminate the psychiatric symptoms. The psychiatric diagnosis must be based on a comprehensive psychiatric evaluation in which the evidence supports the conclusion of a psychiatric diagnosis as required by W212. The focus of active treatment, in this instance, would be on the mental health of the individual. Drugs from categories other than the principle drug classes that have behavior controlling properties (e.g., antipsychotic, antianxiety, and antidepressants) are sometimes used to control inappropriate behavior. Examples include the use of propranolol (Inderal), which is classified as an antihypertensive and antianginal drug, for self-injurious behavior, and carbamazepine (Tegretol), which is an anticonvulsant, for aggression. The regulation was written to encompass any drug when its use is for purposes of controlling inappropriate behavior. This requirement does not apply to drugs, such as propranolol, when they are used to treat medical conditions. However,

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		if their use (e.g. dose, duration, etc.) indicates that they are being used to control inappropriate behavior, the interdisciplinary team must be involved in the decision to use them, and they must be incorporated into the active treatment program plan. In order for an individual to receive dental or medical treatment, the physician may need to prescribe a sedative as part of the normal medical management for that individual. This situation, occurring rarely, would not require an active treatment program targeted toward elimination of the behavior. The decision to use sedation for medical appointments must be made on an individual basis, and with input from the interdisciplinary team. When the individual is regularly exhibiting behaviors that are interfering with the ability to receive routine medical and dental treatment, then use of the sedative is required to be incorporated into a specific active treatment program. §483.450(e)(2) PROBES: Is there documentation that alternative interventions have been considered and tried where appropriate? Is there a pattern of prescription of the same drug used for many individuals, regardless of the problem? Is the overall rate of psychotropic medication usage appropriate to the nature of the population served (e.g., in relation to case mix)? Is there evidence that the individual can be and is placed on psychotropic medications without a full review and the protection processes of these requirements? Is there an identifiable working mechanism to reduce or eliminate the need for psychotropic drug use on each affected individual? Are data collected so that the effect of drug usage can be assessed? Does the physician, psychologist, pharmacist, nurse, and other program and health staff work together to reduce psychotropic drug utilization? Are drug reduction plans actually implemented as indicated by reaching criteria in the behavior management programs?
W313	(3) Drugs used for control of inappropriate behavior must not be used until it can be justified that the harmful effects of the behavior clearly outweigh the potentially harmful effects of the drugs.	§483.450(e)(3) FACILITY PRACTICES: The risk(s) associated with the drug being used is consistent with the type and severity of the behavior/symptoms it is intended to affect.

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	(4) Drugs used for control of inappropriate behavior must be- -	
	(i) Monitored closely,	
W314	in conjunction with the physician and the drug regimen review requirement at §483.460(j),	§483.450(e)(4)(i) FACILITY PRACTICES: The physician and the pharmacist regularly review use of medication for its effectiveness in changing the targeted behavior/symptoms, untoward side effects, contraindications for continued use, and communicate this information to relevant staff.
W315	for desired responses and adverse consequences by facility staff; and	§483.450(e)(4)(i) FACILITY PRACTICES: Staff are aware of what response the drug is expected to achieve, what side effects to watch for, and communicate this information to the appropriate persons. §483.450(e)(4)(i) GUIDELINES: Unless the physician regularly evaluates the individual and meets with those who work most closely with the individual to review treatment progress, it will be difficult to assess whether the individual responded positively to the treatment. Since each drug has a specific profile of side effects, potential reactions should be looked for by direct examination and questioning. It is important that everyone who works with the individual be aware of the conclusion drawn from these drug reviews. In addition to monitoring at regular intervals, the individual should be assessed at the time the medication is changed, as well. Individuals receiving long term antipsychotic drug therapy should be examined regularly for motor restlessness, such as Parkinsonian symptoms or tardive dyskinesia. §483.450(e)(4)(i) PROBES: How does the physician monitor usage of drugs prescribed and is this monitoring and decision-making for drug usage a part of the team process or is it done in isolation by the medical staff? Is there sufficient time for the physician to review the individuals with the team? What do staff report about the medications the individual receives? Their purpose? Side effects? What would they do if side effects suddenly appeared (e.g., extrapyramidal side effects in a person on anti-psychotic drugs)? Is there evidence that the effects of the therapeutic intervention are being assessed and modified in light of the presence or absence of the desired response? In light of the emergence of side effects?
	(ii) Gradually withdrawn	

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W316	at least annually	§483.450(e)(4)(ii) FACILITY PRACTICES: A gradual withdrawal occurs annually or sooner if warranted by progress to the criteria for reduction established in the individual program plan, by the particular drug which is being used, or the specific condition for which the drug is being prescribed.
W317	in a carefully monitored program conducted in conjunction with the interdisciplinary team, unless clinical evidence justifies that this is contraindicated.	§483.450(e)(4)(ii) FACILITY PRACTICES: The IDT is aware of and involved in planning the drug reduction program and participates in its implementation and monitoring. Progress or regression of the individual is monitored and taken into consideration in determining the rate of withdrawal and whether to continue withdrawal. In the absence of an annual drug withdrawal program, there must be strong, objective clinical evidence (e.g., results of previous reduction, research-based justification, etc.) which supports that decision. Changes in the individual, his environment or program is taken into consideration in determining the validity of this evidence. §483.450(e)(4)(ii) GUIDELINES: Planned drug withdrawals must be carefully instituted. For example, usage of antipsychotic drug therapy may not only cause tardive dyskinesia but may mask the clinical manifestations of tardive dyskinesia during treatment. This requirement applies only to drugs prescribed to modify behavior; therefore, if Thorazine is prescribed to decrease aggressive behavior, the annual drug withdrawal requirement applies. However, if Phenobarbital is prescribed to prevent seizures, or Insulin is prescribed to control diabetes, then this requirement does not apply. In determining whether there is clinical contraindication to the annual drug withdrawal, the physician and interdisciplinary team should consider the individual's clinical history, diagnostic/behavioral status, previous reduction/discontinuation attempts, and current regimen effectiveness. The individual's current clinical status or the nature of a psychiatric illness may indicate that gradual withdrawal of the drug is unwise at this time. It is not acceptable, however, to preclude a gradual drug withdrawal for a person, including a person with a psychiatric impairment, merely because of the possibility that his or her behavior may be exacerbated. Data which shows a direct relationship between past attempts at withdrawal, and an increase in the targeted behavior or symptoms should be available to support the decision not to attempt a gradual withdrawal. This data should reflect the programmatic interventions utilized to respond to the behavior prior to determining that gradual withdrawal is contraindicated. The team should periodically re-evaluate the decision not to attempt a gradual withdrawal based on the individual's progress or other changes in clinical status.

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		§483.450(e)(4)(ii) PROBES: Are staff aware of possible withdrawal symptoms, and are plans developed to assist the individual through these periods of stress? Is drug therapy prescribed for an indefinite period of time?

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W318	§483.460 Condition of participation: Health care services.	§483.460 COMPLIANCE PRINCIPLES: The Condition of Participation of Health Care Services is met when: o Individuals receive preventative services and prompt treatment for acute and chronic health conditions; and o Individuals' health is improved or maintained unless the deterioration is due to a documented clinical condition for which deterioration or lack of improvement is an accepted prognosis. The Condition of Participation of Health Care Services is not met when individuals do not receive adequate health care monitoring and services, including appropriate and timely follow-up, based upon their individualized need for service.
	(a) Standard: Physician services.	
W319	(1) The facility must ensure the availability of physician services 24 hours a day.	§483.460(a)(1) GUIDELINES: Procedures must be established that provide steps to be followed when the designated physician is not available. Staff should be aware of procedures for contacting physicians in the event of an emergency.
W320	(2) The physician must develop, in coordination with licensed nursing personnel, a medical care plan of treatment for a client if the physician determines that an individual client requires 24-hour licensed nursing care.	§483.460(a)(2) GUIDELINES: The use of a medical care plan is intended only for those who are so ill or so at medical risk that 24-hour licensed nursing care is essential. A medical care plan need not be developed unless the individual requires licensed nursing care around the clock. Thus, individuals with chronic, but stable health problems such as controlled epilepsy, diabetes, etc. do not require a medical care plan. It is not required that an individual have a health deficit and/or a medical care plan in order to receive ICF/MR services. The regulation is sufficiently flexible that the entire range of individuals, from those in good physical health to those who are very medically fragile, may be served. A medical care plan may be temporary, in that it may be established to address acute health problems and then discontinued when those problems are resolved.
W321	This plan must be integrated in the individual program plan.	§483.460(a)(2) FACILITY PRACTICES: The medical care plan is a part of the IPP and, therefore, known and available to the inter-disciplinary team (IDT) and all staff working with the individual. Training programs take into consideration medical needs/status.

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	(3) The facility must provide or obtain	
W322	preventive and general care	§483.460(a)(3) FACILITY PRACTICES: The individual receives the services indicated by his/her health status. There is follow-up to recommendations for referrals to specialists, specific examinations or evaluations, and treatments. §483.460(a)(3) GUIDELINES: Medical services are provided as necessary to maintain an optimum level of health for each individual and to prevent disability. Medical services include evaluation, diagnosis and treatment, as needed, by individuals. Medical services, including sources for laboratory, radiology, and other medical and remedial services available to the individual must be provided if not provided in-house. There must be a written agreement that specifies the responsibilities of the facility and outside provider. (See §483.410(a).) §483.460(a)(3) PROBES: Are referrals made to other specialists when appropriate? Are referrals followed up? Are women provided with gynecological services? Are individuals referred to neurologists, if they have poor seizure control over a long period of time? A noted toxicity of seizure medications? Are individuals with apparent mental illness (e.g., depression, psychosis, obsessive/compulsive disorder) referred to specialists for proper diagnosis and treatment?
	as well as annual physical examinations of each client that at a minimum include the following:	
W323	(i) Evaluation of vision and hearing;	§483.460(a)(3)(i) FACILITY PRACTICES: The individual receives a screening of vision and hearing at least annually. Observation, documentation, or interview indicates that any vision or hearing problems which are suspected by staff are reported and follow-up assessments done. Special studies are conducted in accordance with the timeframe recommended by the relevant specialist when more traditional approaches to evaluation cannot be conducted.

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		§483.460(a)(3)(i) GUIDELINES: This standard is intended to be an annual screening so that individuals who need further indepth examination can be identified. If hearing screens are conducted annually by speech-language pathologists or audiologists the physical exam does not need to repeat this information. Information relevant to knowing if the individual can see or hear, and how well, is tantamount for designing an appropriate active treatment strategy responsive to need. If an individual's vision or hearing can only be assessed through examinations conducted by specialists (e.g., comprehensive ophthalmological examinations and evoked response audiometry (ERA)), these tests need not be conducted yearly, but rather upon specialist's recommendations. In such situations determine if yearly, the team evaluates the individual's vision and hearing response behaviors for change, and makes referrals, if necessary. §483.460(a)(3)(i) PROBES: Do assessments of vision and hearing include acuity measures, as well as physiological measures, as appropriate?
W324	(ii) Immunizations, using as a guide the recommendations of the Public Health Service Advisory Committee on Immunization Practices or of the Committee on the Control of Infectious Diseases of the American Academy of Pediatrics;	§483.460(a)(3)(ii) GUIDELINES: These immunization guides can be obtained from the American Academy of Pediatrics, Elk Grove, IL, telephone: (708) 228-5005, or from the Centers for Disease Control, Division of Immunization Center for Preventive Services, telephone: (404) 639-8215.
W325	(iii) Routine screening laboratory examinations as determined necessary by the physician,	§483.460(a)(3)(iii) GUIDELINES: This does not preclude screening tests available to the general public such as tests for urine sugar. §483.460(a)(3)(iii) PROBES: Has physician justification been provided when the physician determines that a standard laboratory test is not necessary for the individual?
W326	and special studies when needed;	

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W327	(iv) Tuberculosis control, appropriate to the facility's population, and in accordance with the recommendations of the American College of Chest Physicians or the section on diseases of the chest of the American Academy of Pediatrics, or both.	§483.460(a)(3)(iv) FACILITY PRACTICES: When one or more individuals display tuberculosis (TB) symptoms, as substantiated by positive lab/x-ray results, appropriate treatment and precautions are in place. §483.460(a)(3)(iv) GUIDELINES: These recommendations can be obtained from the American Academy of Pediatrics, Elk Grove Village, IL, telephone: (708) 228-5005, or the American College of Chest Physicians, Northbrook, IL, telephone: (708) 498-1400. The American College of Chest Physicians and the American Academy of Pediatrics endorse the recommendations of the Center for Disease Control and Prevention, Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities, (most recent edition). The facility should have in place a system appropriate to its population for the identification, reporting, investigation, and control of TB in order to prevent its transmission within the facility. This system should include policies and procedures for screening new employees, new clients, and other people who interact on a consistent basis with individuals residing in the facility; for reporting positive TB test results to the appropriate State authorities; for the investigative procedures that would be put in place should an individual or staff person test positive for TB; and for the evaluation of the effectiveness of the entire system. There should be arrangements with outside service providers, when needed, to ensure that any individual who tests positive for TB will receive appropriate medical treatment. Also, the system should address the issue of any staff member who tests positive for TB. The Occupational Health and Safety Administration (OSHA) requirements regarding exposure control plans and activities may also apply.
W328	(4) To the extent permitted by State law, the facility may utilize physician assistants and nurse practitioners to provide physician services as described in this section.	
	(b) Standard: Physician participation in the individual program plan.	
	A physician must participate in- -	
W329	(1) The establishment of each newly admitted client's initial individual program plan as required by §456.380 of this chapter that specifies plan of care requirements for ICFs; and	§483.460(b)(1) GUIDELINES: During the admission process, which extends from the time the individual is admitted to the time the initial IPP is completed, a physician is required to ensure that an assessment of the individual's medical status is thoroughly considered and addressed by the team as it develops the IPP. The physician's input may be by means of written reports, evaluations, and recommendations. 42 CFR 456.380 requires that a physician must establish a written plan of care for each

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		applicant or recipient before admission to an ICF. This is done in conjunction with the interdisciplinary team. (See §483.440(c).) The written plan of care required by §456.380 and the IPP required by §483.440(c) may be the same document, which can fulfill both requirements.
W330	(2) If appropriate, physicians must participate in the review and update of an individual program plan as part of the interdisciplinary team process either in person or through written report to the interdisciplinary team.	§483.460(b)(2) FACILITY PRACTICES: Based on the needs and health status of the individual, the physician participates in the IPP review and update in such a way as to ensure accurate and appropriate consideration of the individual's health status and functioning in the plan's creation and implementation. §483.460(b)(2) GUIDELINES: The need for physician participation is determined by the medical needs of the individual. How the participation (whether through written report, telephone consultation, attendance at the meeting, etc.) is to be accomplished is left to the discretion of the facility.
	(c) Standard: Nursing services.	
W331	The facility must provide clients with nursing services in accordance with their needs.	§483.460(c) FACILITY PRACTICES: Individuals on a medical care plan receive 24-hour nursing service as indicated by that plan. Individuals not on a medical care plan receive services as indicated by the assessment, the IPP, and in accordance with any changes in health status.
	These services must include- -	
W332	(1) Participation as appropriate in the development, review, and update of an individual program plan as part of the interdisciplinary team process;	§483.460(c)(1) FACILITY PRACTICES: A licensed nurse participates as a member of the IDT in the IPP process for all individuals on a medical care plan and, if individual needs dictate, for other individuals as well. §483.460(c)(1) GUIDELINES: Unless the individual is on a medical care plan, this participation may be through a written report.
W333	(2) The development, with a physician, of a medical care plan of treatment for a client when the physician has determined that an individual client requires such a plan;	§483.460(c)(2) GUIDELINES: See also W416.

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	(3) For those clients certified as not needing a medical care plan, a review of their health status which must- -	
W334	(i) Be by a direct physical examination;	§483.460(c)(3)(i) GUIDELINES: A direct physical examination means a visual review of the body as well as examination of body systems that might be necessary. This includes observing for any clues (including visual, tactile, nonverbal gestures, grimaces, etc.) to detect if there is a potential for needed follow-up and monitoring. A paper review of the individual's medical record and health statistics is not a direct physical examination. If an individual is on a medical care plan, it is not necessary to perform the quarterly direct nursing physical examination. §483.460(c)(3)(i) PROBES: An example of a body system review is foot care, and appropriate questions to ask in assessing the status of foot care would be: o Is there evidence of abnormal swelling? o Is skin supple? o Are there signs of skin cracking or breaking? o Are ulcers present? o Is fungus present? o Are there signs of ingrown nails? o Are nails painful when pressed? o Is there dampness between toes?
W335	(ii) Be by a licensed nurse;	§483.460(c)(3)(ii) GUIDELINES: The term "licensed nurse" for purposes of this requirement means a registered nurse, a licensed practical nurse or a licensed vocational nurse. A facility is allowed to use a physician, in place of a licensed nurse, although this is certainly not required.
W336	(iii) Be on a quarterly or more frequent basis depending on client need;	§483.460(c)(3)(iii) GUIDELINES: "On a quarterly basis" means that the examination must be performed within the month in which the end of the quarter falls. If during the course of a year, there were three examinations conducted by a licensed nurse and one annual examination performed by a physician, each of which is performed within the month in which the end of the quarter or year falls, the intent of this requirement is met.
W337	(iv) Be recorded in the client's record; and	§483.460(c)(3)(iv) GUIDELINES: The record includes the date of the exam.
W338	(v) Result in any necessary action (including referral to a physician to address client health problems).	§483.460(c)(3)(v) FACILITY PRACTICES: The nurse makes appropriate referrals and communicates or addresses problems if the quarterly exam yields physical findings considered abnormal or atypical for the individual.

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		This communication results in timely changes in the individual's health care when needed. §483.460(c)(3)(v) GUIDELINES: Some physical findings discovered by the nurse while conducting the physical exam will not necessarily result in referral to the physician. This practice is acceptable if the nurse is acting within the scope of the Nurse Practice Act of the State in which he or she is licensed. §483.460(c)(3)(v) PROBES: What is the feedback mechanism to the physician? Is there a traceable relationship between facility staff and physicians that results in timely changes in individuals' health care?
W339	(4) Other nursing care as prescribed by the physician or as identified by client needs; and	§483.460(c)(4) FACILITY PRACTICES: Health and wellness are actively promoted, problems are attended to before they become serious, and steps are taken to prevent the recurrence of such problems while responding promptly to individual's needs. Nursing interventions are implemented as required by the IPP. §483.460(c)(4) GUIDELINES: This includes nursing care for individuals without a medical care plan. §483.460(c)(4) PROBES: Is skin integrity maintained and breakdown prevented? Are measures used to prevent skin breakdown (e.g., padding pressure points, use of emollients)?
	(5) Implementing with other members of the interdisciplinary team, appropriate protective and preventive health measures that include, but are not limited to- -	
W340	(i) Training clients and staff as needed in appropriate health and hygiene methods;	§483.460(c)(5)(i) FACILITY PRACTICES: Individuals and staff receive direct training in how to care for health needs/conditions, personal hygiene, health maintenance, and disease prevention. Individuals are trained in areas such as taking medicine, sexuality, family planning, prevention of sexually transmitted diseases, control of other infectious diseases, self-monitoring of health status and self-prevention of health problems, etc., when such training is relevant to the needs of the individuals.

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		§483.460(c)(5)(i) GUIDELINES: Facility staff need to know what the limits of their responsibilities are with medically involved individuals, and how to teach individuals on a continuing basis how to take care of minor accidents until further care can be provided.
W341	(ii) Control of communicable diseases and infections, including the instruction of other personnel in methods of infection control; and	
W342	(iii) Training direct care staff in detecting signs and symptoms of illness or dysfunction, first aid for accidents or illness, and basic skills required to meet the health needs of the clients.	§483.460(c)(5)(iii) FACILITY PRACTICES: Direct care staff receive training in skills relevant to the population of individuals served by the facility.
	(d) Standard: Nursing staff.	
W343	(1) Nurses providing services in the facility must have a current license to practice in the State.	
W344	(2) The facility must employ or arrange for licensed nursing services sufficient to care for clients' health needs including those clients with medical care plans.	§483.460(d)(2) FACILITY PRACTICES: The facility provides for nursing services based on the health needs and conditions of individuals residing there. Individual health care needs are being met in a timely manner by the available nursing staff. §483.460(d)(2) GUIDELINES: In evaluating whether or not there is sufficient licensed nursing staff, evaluate the need for licensed nursing care represented by the health characteristics of the individuals served (as described in physical exam results, IPPs, and medical care plans) in relation to the competency and qualifications represented by the staff who provide care (through the onsite survey). Make a judgment about the sufficiency of nursing staff to care for this particular population. §483.460(d)(2) SURVEY PROCEDURE: In most circumstances, when one or more individuals in the facility require a medical care plan (i.e., the medical risk of an individual is so potentially life threatening that the individual requires continuous licensed nursing care in order to ensure his or her health and safety,) then that individual's needs are such that licensed personnel must be present. In the presence of such a situation, validate that 24-hour on duty staffing patterns of licensed personnel are provided.

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W345	(3) The facility must utilize registered nurses as appropriate and required by State law to perform the health services specified in this section.	
W346	(4) If the facility utilizes only licensed practical or vocational nurses to provide health services, it must have a formal arrangement with a registered nurse to be available for verbal or onsite consultation to the licensed practical or vocational nurse.	
W347	(5) Non-licensed nursing personnel who work with clients under a medical care plan must do so under the supervision of licensed persons.	
	(e) Standard: Dental services	
W348	(1) The facility must provide or make arrangements for comprehensive diagnostic and treatment services for each client from qualified personnel, including licensed dentists and dental hygienists either through organized dental services in-house or through arrangement.	
W349	(2) If appropriate, dental professionals must participate, in the development, review and update of an individual program plan as part of the interdisciplinary process either in person or through written report to the interdisciplinary team.	§483.460(e)(2) FACILITY PRACTICES: Based on the needs of the individual, dental personnel participate in development and monitoring the IPP to ensure accurate and appropriate consideration of the individual's dental needs in the plan's design and implementation.

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W350	(3) The facility must provide education and training in the maintenance of oral health.	§483.460(e)(3) FACILITY PRACTICES: Training in the maintenance of oral hygiene is provided to individuals who require it, and to those who are responsible for carrying out such activities.
	(f) Standard: Comprehensive dental diagnostic services.	
	Comprehensive dental diagnostic services include	
W351	(1) A complete extraoral and intraoral examination, using all diagnostic aids necessary to properly evaluate the client's condition not later than one month after admission to the facility (unless the examination was completed within twelve months before admission);	§483.460(f)(1) GUIDELINES: A "month" is defined as the interval between the date of admission and close of business of the corresponding day in the following month.
	(2) Periodic examination and diagnosis performed	§483.460(f)(2) GUIDELINES: The requirement applies to all individuals (including those without teeth), and more frequently as dictated by the individual's needs.
W352	at least annually,	
W353	including radiographs when indicated and detection of manifestations of systemic disease; and	
W354	(3) A review of the results of examination and entry of the results in the client's dental record.	
	(g) Standard: Comprehensive dental treatment.	§483.460(g) GUIDELINES: Comprehensive dental treatment might include, but is not limited to:
	The facility must ensure comprehensive dental treatment services that include- -	1. Periodic examination and diagnosis, including radiographs, when indicated and detection of all manifestations of systemic disease; 2. Elimination of infection or life hazardous oral conditions, oral cancer, or cellulitis;

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		3. Treatment of injuries; 4. Restoration of decayed or fractured teeth; 5. Retention or recovery of space between teeth in children, when indicated; 6. Replacement of missing permanent teeth, when indicated; and 7. Appropriate pain control procedures for optimal care of the patient.
W355	(1) The availability for emergency dental treatment on a 24-hour-a-day basis by a licensed dentist; and	
W356	(2) Dental care needed for relief of pain and infections, restoration of teeth, and maintenance of dental health.	§483.460(g)(2) PROBES: Are individuals' dental needs neglected until there is pain or other emergency? Do examinations indicate that services were furnished, rather than notes indicating that the individual was "unable to be examined" or "as best as can be determined?"
	(h) Standard: Documentation of dental services.	
	(1) If the facility maintains an in-house dental service, the facility must	
W357	keep a permanent dental record for each client,	
W358	with a dental summary maintained in the client's living-unit.	§483.460(h)(1) GUIDELINES: A "dental summary" means a brief written report of each visit to the dentist and includes any care instructions to be followed-up by facility staff as a result of treatment.
	(2) If the facility does not maintain an in-house dental service, the facility must	
W359	obtain a dental summary of the results of dental visits	§483.460(h)(2) GUIDELINES: The dentist used by the facility must agree to release the records and final recommendations for future care when the individual is discharged or discontinues service with the dentist.
W360	and maintain the summary in the client's living unit.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(i) Standard: Pharmacy services.	
W361	The facility must provide or make arrangements for the provision of routine and emergency drugs and biologicals to its clients. Drugs and biologicals may be obtained from community or contract pharmacists or the facility may maintain a licensed pharmacy.	483.460(i) GUIDELINES: Emphasis is placed on the provision of the service, and not on its method of delivery. Whether the facility utilizes the unit dose, individual prescription or a combination of these systems, or whether the facility has its own pharmacy or provides the service through arrangement with a community pharmacy, the emphasis is on the accuracy of the drug distribution system and the effectiveness of the drug therapy.
	(j) Standard: Drug regimen review.	
W362	(1) A pharmacist with input from the interdisciplinary team must review the drug regimen of each client at least quarterly.	483.460(j)(1) FACILITY PRACTICES: The IDT provides the pharmacist with relevant input for the drug regimen review (e.g., changes in behavior, new medication the person has begun taking, etc.). Reviews are performed as often as individual need dictates, but not less than quarterly. §483.460(j)(1) GUIDELINES: The pharmacist should review on a more frequent basis the drug regimen of individuals whose response indicates problems with drug therapy. Refer to the "Indicators for Surveyor Assessment of the Performance of Drug Regimen Reviews" as stated in Appendix N to the State Operations Manual (Pharmaceutical Service Requirements in Long Term Care Facilities) to evaluate the drug regimen review done by the pharmacist. §483.460(j)(l) PROBES: Does this review look at the individual's response to the drug?
W363	(2) The pharmacist must report any irregularities in clients' drug regimens to the prescribing physician and interdisciplinary team.	483.460(j)(2) FACILITY PRACTICES: The pharmacist identifies apparent irregularities and determines their significance. The pharmacist reports apparent irregularities which are significant to the physician and the IDT. The physician and IDT are aware of all irregularities in the individual's drug regimen. §483.460(j)(2) GUIDELINES: The physician and interdisciplinary team must consider the report of the pharmacist and determine whether to accept or reject the recommendations in the report. The pharmacist is not required to repeatedly report the same minor irregularities which have already been considered by the physician and the interdisciplinary team, but were rejected based upon the individual's specific condition.

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		§483.460(j)(2) SURVEY PROCEDURE: Review the drug regimen reviews of sampled individuals in order to determine if the pharmacist has appropriately reviewed the drug regimen on a quarterly basis. Refer to the "Indicators for Surveyor Assessment of the Performance of Drug Regimen Reviews" as stated in Part One of Appendix N (Pharmaceutical Service Requirements in Long Term Care Facilities). Appendix N lists many apparent drug irregularities that can occur. The following exceptions apply to the "List of Apparent Irregularities" on pages N-7 and N-8: 1. "Use of a listed anti-psychotic drug unless one of the following specific conditions exists..." At the present time we have not developed a list of conditions which limit the use of anti-psychotic drugs for individuals in ICFs/MR. 2. "Use of anti-psychotic drugs in the absence of gradual dose withdrawal attempted every six months..." In ICFs/MR, the requirement is that gradual reduction be attempted at least annually unless clinically contraindicated. See W316 & W317. 3. "The use of a p.r.n. [as needed] anti-psychotic drug more than five times..." Standing or as needed programs to control inappropriate behavior are not permitted under the ICF/MR regulations. A drug may be used in an emergency situation, but emergency drug usage can not continue until that usage has been approved by the interdisciplinary team and included in the active treatment program. See W290, W311 and W312.
W364	(3) The pharmacist must prepare a record of each client's drug regimen reviews and the facility must maintain that record.	
W365	(4) An individual medication administration record must be maintained for each client.	§483.460(j)(4) GUIDELINES: Each dose of medication, whether self-administered or not, shall be properly recorded in the individual's record. The intent of this requirement is to maintain a record of drugs administered.
W366	(5) As appropriate the pharmacist must participate in the development, implementation, and review of each client's individual program plan either in person or through written report to the interdisciplinary team.	§483.460(j)(5) FACILITY PRACTICES: For individuals who have complex drug therapy, are taking medications which may have serious side effects or interactions, or whose team requires medication information in order to design the IPP, the pharmacist participates in the IPP process in order to address these issues. §483.460(j)(5) GUIDELINES: This regulation does not exclude the pharmacist from the evaluation process, but the pharmacist can best determine how to expend his/her efforts most productively in service to individuals at the facility.

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	(k) Standard: Drug administration.	
W367	The facility must have an organized system for drug administration that identifies each drug up to the point of administration.	
	The system must assure that- -	
W368	(1) All drugs are administered in compliance with the physician's orders;	
W369	(2) All drugs, including those that are self-administered, are administered without error;	§483.460(k)(2) GUIDELINES: A medication "error" is a discrepancy between what the physician has ordered, and what you observe during the drug pass observation. The regulation does not allow for any medication errors. "Self administered" means administration of medications by the individual, independent of a staff person obtaining, selecting, and preparing the medications for the individual. This includes all usage forms (oral, injections and suppositories). The individual should be trained until he/she can perform this function without error. §483.460(k)(2) SURVEY PROCEDURE: Use the observation technique to determine medication errors. The observation technique involves observing the administration of drugs, recording what is observed, and reconciling the record of observation with the physician's orders to determine whether or not medication errors have occurred. Do not rely on paper review to determine medication errors. Detection of blank spaces on the medication administration record does not constitute the detection of actual medication errors. Paper review only identifies possible errors. Observation Technique Follow these steps to detect medication errors: 1. Identify the drug product. Determine what drugs, in what strength and dosage forms, etc., are being administered. There are two principle ways of doing this. In most cases, they are used in combination. o Identify the product by its size, shape and color. Many products have a distinctive size, shape or color. However, this technique can be problematic because not all products are distinctive.

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		o Identify the product by observing the label. When the punch card or unit dose system is used, you can usually observe the label and adequately identify the drug product. When the vial system is used, observing the label is sometimes difficult. Ask the person administering medications to identify the drug product. 2. Observe the administration of drugs. Record your observations in your notes. Follow the person administering medications and observe the individuals receiving drugs (e.g., actually swallowing oral dosage forms). Be as neutral and as unobtrusive as possible during this process. Watch 16 drug doses being administered to the individuals residing in the facility, or observe a 100% sample of the residents in the facility whichever is smaller. For example, in a four bed facility with each individual taking two morning doses, you would watch a 100% sample of the individuals since only eight doses would have been administered. In an eight bed facility with each individual taking four morning doses you would observe a sample of 16 doses being administered. In a large facility, a larger sample (40 to 50 doses) taken from different units in the facility should be observed to ensure that an adequate sample of the drug distribution system has been evaluated. It is usually preferable to watch the morning pass because more doses per individual are administered at that time; however, you may observe the pass at any time. Observe more than one staff member administering drugs, if possible. You may observe the drugs being administered in the individual's living quarters or in the day program if the day program is operated by the ICF/MR on its grounds (i.e., the day program is not a separately certified entity). If there are individuals at the facility who self-administer medications, attempt to observe the self-administration (see W373). Respect the individual's right to privacy by verbally asking the individual for permission to observe. Note every detail about drug administration in your notes. For example, "eye drops administered to both eyes" or "nurse took pulse" or "all drugs crushed and administered in applesauce." 3. Record, in your notes, the most current physician's orders for those individuals who were observed receiving medications. The latest recapitulation of drug orders is sufficient for determining whether a valid order exists, provided that the physician has signed the "recap." The signed "recap" and subsequent orders constitute a legal authorization to administer the drug. You should now have a complete record of what you observed, and what should have occurred according to the physician orders.

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		4. Reconcile your record of observation with the physician's orders. Compare your record of observation to the most current signed orders for drugs. o For each drug on your list: Was it administered according to the physician's orders? For example, in the correct strength, by the correct route? Was there a valid order for the drug? o For drugs not on your list: Are there orders for drugs that should have been administered, but were not? Such circumstances represent omitted doses, which is one of the most frequent types of errors. 5. Determine the number of errors by adding the errors for each individual. Before concluding that an error has occurred, discuss the apparent error with the person who administered the drug. There may be a logical explanation, such as a more recent physician order which you have not seen. 6. Timing errors: If a drug is ordered before meals (AC) and administered after meals (PC) or vice versa, always count this as an error. If the drug is administered more than 60 minutes later or earlier than its scheduled administration time, count this as an error ONLY IF THAT WRONG TIME ERROR CAN CAUSE THE INDIVIDUAL DISCOMFORT OR JEOPARDIZE THE RESIDENT'S HEALTH AND SAFETY. Counting a drug with a long half-life (beyond 24 hours) as a wrong time error when it is 15 minutes late is improper because there is no significant impact on the individual. To determine the scheduled administration time, examine the facility's policy relative to dosing schedules.
W370	(3) Unlicensed personnel are allowed to administer drugs only if State law permits;	§483.460(k)(3) GUIDELINES: "Unlicensed personnel" of the facility does not refer to the situation of individuals administering their own medication. Unlicensed personnel administer only those forms of medication which State law permits.
W371	(4) Clients are taught to administer their own medications if the interdisciplinary team determines that self-administration of medications is an appropriate objective, and if the physician does not specify otherwise;	§483.460(k)(4) FACILITY PRACTICES: Based on assessment results and IDT discussion, the individual is instructed in skills leading to self-administration of medication, when appropriate, based on the person's functional abilities. No individual is precluded from training based solely on diagnosis or level of functioning. §483.460(k)(4) PROBES: Is there a pattern of refusal to allow self-medication? How is the health and safety of individuals assured during training for self-medication?

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W372	(5) The client's physician is informed of the interdisciplinary team's decision that self-administration of medications is an objective for the client;	
W373	(6) No client self-administers medication until he or she demonstrates the competency to do so;	§483.460(k)(6) FACILITY PRACTICES: Individuals are supervised during self-administration training programs. Individuals who demonstrate and master self-administration at the level and frequency specified, administer independent of staff. §483.460(k)(6) GUIDELINES: Do not expect individuals served to be more knowledgeable than members of the general public in order to self-administer medication. There is no requirement for the individual to be able to state both the generic and brand names of the medication being taken, nor is it expected that the individual be able to list all potential side effects of the medication. The test of competency to self-administer is whether the individual can take the correct medication, in the correct dosage, at the correct time. §483.460(k)(6) PROBES: Is there a pattern that all individuals self-medicate whether they can demonstrate the skill or not?
W374	(7) Drugs used by clients while not under the direct care of the facility are packaged and labeled in accordance with State law;	§483.460(k)(7) GUIDELINES: When individuals go out of a facility for home visits, or to attend workshops or school, drugs they are taking must be packaged and labeled in accordance with State law by a responsible person approved to administer medications. Be aware whether or not there are applicable State laws which may allow packaging by someone other than the pharmacist. The test of adequacy of packaging and labeling is whether or not other persons administering medications are able to identify the individual's medication, method of administration, contraindications, if appropriate, and administration schedule.
	(8) Drug administration errors and adverse drug reactions are	
W375	recorded	
W376	and reported immediately to a physician.	

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	(l) Standard: Drug storage and recordkeeping.	
	(1) The facility must store drugs under proper conditions of	
W377	sanitation,	
W378	temperature,	
W379	light,	
W380	humidity,	
W381	and security.	
W382	(2) The facility must keep all drugs and biologicals locked except when being prepared for administration.	
W383	Only authorized persons may have access to the keys to the drug storage area.	§483.460(l)(2) GUIDELINES: "Authorized persons" must be restricted to those who administer the drugs and nursing supervisors (if any). No other personnel should have access to these keys.
W384	Clients who have been trained to self administer drugs in accordance with §483.460(k)(4) may have access to keys to their individual drug supply.	§483.460(l)(2) GUIDELINES: Drugs that are self-administered do not have to be double locked. The purpose for the double locking is to limit access to scheduled drugs. Since the individual is generally the only one who has access to his/her drug supply (with perhaps the exception of a facility's Director of Nursing Services, who may have access to all of the facility's drug supplies), there is no need to further limit access.
W385	(3) The facility must maintain records of the receipt and disposition of all controlled drugs.	§483.460(l)(3) GUIDELINES: The facility may also use the medication administration record for purposes of documenting receipt and disposition of controlled drugs. By recording the amount received, a record of the receipt and disposition, can be realized.
W386	(4) The facility must, on a sample basis, periodically reconcile the receipt and disposition of all controlled drugs in schedules II through IV (drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801 et seq., as implemented by 21 CFR Part 308).	§483.460(l)(4) GUIDELINES: Reconciliation of receipt and disposition of controlled drugs need not be done on each shift. If periodic (e.g., weekly or monthly) reconciliations indicate losses, more frequent reconciliation (daily or by shift) may need to be performed to identify and stop losses.

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W387	(5) If the facility maintains a licensed pharmacy, the facility must comply with the regulations for controlled drugs.	
	(m) Standard: Drug labeling.	
	(1) Labeling of drugs and biologicals must- -	
W388	(i) Be based on currently accepted professional principles and practices; and	
W389	(ii) Include the appropriate accessory and cautionary instructions, as well as the expiration date, if applicable.	
	(2) The facility must remove from use- -	
W390	(i) Outdated drugs; and	
W391	(ii) Drug containers with worn, illegible, or missing labels.	
W392	(3) Drugs and biologicals packaged in containers designated for a particular client must be immediately removed from the client's current medication supply if discontinued by the physician.	§483.460(m)(3) GUIDELINES: If a physician discontinues a drug for a particular individual, that particular drug supply should be removed from its usual storage area. This precludes that drug from being administered to the individual in error.
	(n) Standard: Laboratory services.	§483.460(n) FACILITY PRACTICES: If the facility performs laboratory services, it has a current, valid certificate for the types of tests it is performing.
W393	(1) If a facility chooses to provide laboratory services, the laboratory must meet the requirements specified in part 493 of this chapter.	§483.460(n) GUIDELINES: A "laboratory service or test" is defined as any examination or analysis of materials derived from the human body for purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.

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W394	(2) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.	A facility performing any laboratory service or test must have applied to HCFA, and received either a certificate of waiver or a certificate of registration. An application for a certificate of waiver may be made if the facility performs only those tests on the waiver list. Those tests are: o Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: - Bilirubin; - Glucose; - Hemoglobin; - Ketone; - Leukocytes; - Nitrite; - pH; - Protein; - Specific gravity; and - Urobilinogen. o Fecal Occult blood; o Ovulation tests - visual color comparison tests for human luteinizing hormone; o Urine pregnancy tests - visual color comparison tests; o Erythrocyte sedimentation rate (non-automated); o Hemoglobin - copper sulfate (non-automated); o Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; o Spun microhematocrit; and o Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. If the facility performs tests, other than those on the waiver list, a certificate of registration is required. These certificates are required regardless of the frequency with which the laboratory services or tests are conducted. When no tests are performed, a certificate is not needed. Facilities only collecting specimens and not performing testing do not need a certificate. A not-for-profit or a State or local government organization may have one certificate covering all the facilities it operates (i.e., all the separately certified residences which fall under its governing body), if no more than a total of 15 types of waivered or moderately complex laboratory tests are used. §483.460(n) SURVEY PROCEDURE: If the facility performs any laboratory service or test (as defined above), ask to see a current valid certificate of waiver, or certificate of registration, whichever is applicable.

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		Some facilities may be exempt from the Clinical Laboratory Improvement Act (CLIA) by virtue of being licensed by a State with a HCFA-approved laboratory licensure program. In this case, the surveyor should ask to see a current valid State laboratory license. Concerns regarding the application of these requirements should be directed to your State laboratory consultant or the HCFA regional office.

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W406	§483.470 Condition of participation: Physical environment.	§483.470 COMPLIANCE PRINCIPLES: The Condition of Participation of Physical Environment is met when: o The environment promotes the health and safety, independence and learning of the individuals who reside there. The Condition of Participation of Physical Environment is not met when: o Environmental conditions interfere with learning and independence (e.g., lack of appropriate assistive devices, accessible bathrooms and closets, house or water temperatures, etc.) to such an extent that the Condition of Participation for Active Treatment is not met. o Individuals are at risk to health and safety due to environmental conditions. o Poor infection control practices are observed and there is a high rate of infections or communicable diseases among the individuals residing in the facility.
	(a) Standard: Client living environment.	
W407	(1) The facility must not house clients of grossly different ages, developmental levels, and social needs in close physical or social proximity unless the housing is planned to promote the growth and development of all those housed together.	§483.470(a)(1) FACILITY PRACTICES: The grouping of individuals in living units takes into consideration the needs, functional levels, ages, interests, social skills and abilities of all residents and does not endanger the health, safety or development of any individual. The living arrangement promotes independence and learning for all individuals who reside there. §483.470(a)(1) GUIDELINES: Individuals should live in the least restrictive grouping in keeping with their level of functioning. Prime consideration in the grouping of individuals is made according to social and intellectual development, friendship patterns, and commonality of interests. The use of "grossly different ages" is intended to ensure, for example, that very young children are not inappropriately housed together with much older individuals. Extreme differences may in some instances actually impede appropriate training and may pose a threat to the safety of younger, more vulnerable individuals.

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W408	(2) The facility must not segregate clients solely on the basis of their physical disabilities. It must integrate clients who have ambulation deficits or who are deaf, blind, or have seizure disorders, etc., with others of comparable social and intellectual development.	§483.470(a)(2) FACILITY PRACTICES: Individuals with and without physical disabilities are integrated in living environments which are designed to meet the needs of all participants. §483.470(a)(2) GUIDELINES: The surveyor should determine if the individuals' skill level, rather than the individuals' physical, sensory or medical disability, justifies the housing pattern.
	(b)Standard: Client bedrooms.	
	(1) Bedrooms must- -	
W409	(i) Be rooms that have at least one outside wall;	
W410	(ii) Be equipped with or located near toilet and bathing facilities;	
W411	(iii) Accommodate no more than four clients unless granted a variance under paragraph (b)(3) of this section;	
	(iv) measure	
W412	at least 60 square feet per client in multiple client bedrooms	
W413	and at least 80 square feet in single client bedrooms; and	
W414	(v) In all facilities initially certified, or in buildings constructed or with major renovations or conversions on or after October 3, 1988, have walls that extend from floor to ceiling.	§483.470(b)(l)(v) GUIDELINES: An "initially certified" facility includes any facility or portion thereof that is certified for participation in Medicaid after a period of non-participation (e.g., if its certification has been terminated or voluntarily withdrawn). Each of the three criteria specified below must exist in order for a facility to qualify as undergoing "major renovations or conversions": o Individuals must vacate the building during the period of renovation or construction;

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		o No Medicaid billing takes place during the period of renovation or construction; and o A resurvey of the building is required before individuals may return to live in the building. Facilities with buildings which were undergoing major renovations and were not reoccupied prior to October 3, 1988, are expected to meet the floor to ceiling wall requirements. This also applies to those facilities with buildings that had plans for renovation approved prior to October 3. There is no provision in the regulation for granting waivers of this requirement. In a facility certified prior to October 3, 1988, if the conditions which define "major renovation or conversion" are avoided during installation of walls to divide "open bay sleeping areas," it is allowable for the walls not to extend from floor to ceiling.
W415	(2) If a bedroom is below grade level, it must have a window that-- (i) Is usable as a second means of escape by client(s) occupying the room; and (ii) Is no more than 44 inches (measured to the window sill) above the floor unless the facility is surveyed under the Health Care Occupancy Chapter of the Life Safety Code, in which case the window must be no more than 36 inches (measured to the window sill) above the floor.	§483.470(b)(2) GUIDELINES: The intent of the regulation is to prohibit the housing of individuals in basements that are entirely below grade. Individuals may be housed on the lower level of housing (e.g., a bi-level house), provided the window height requirements are met.

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W416	(3) The survey agency may grant a variance from the limit of four clients per room only if a physician who is a member of the interdisciplinary team and who is a qualified mental retardation professional-- (i) Certifies that each client to be placed in a bedroom housing more than four persons is so severely medically impaired as to require direct and continuous monitoring during sleeping hours; and (ii) Documents the reason why housing in a room of only four or fewer persons would not be medically feasible.	§483.470(b)(3) GUIDELINES: The only acceptable reason for individuals to be housed in bedrooms serving more than four people is because the individual is in very fragile health and needs extensive life support services, such as posturing for clearing the airways, or monitoring for uncontrolled seizures. If more than four people are housed together in the same room, the number should remain small, and each individual placed in the grouping must have a high level of medical monitoring need. Most extensive life support services, by their very nature are able to be provided by licensed personnel alone, or only under the direct visual supervision of licensed personnel. The presence of a medical care plan is not required because all such life threatening possibilities are difficult to predict. However, the greatest majority of individuals who might qualify for this variance will be on a medical care plan. See §2140 for the documentation required for a medical variance. §483.470(b)(3) SURVEY PROCEDURE: The absence of a medical care plan for individuals for whom a variance is requested constitutes a "flag", and will necessitate an investigation into the individual circumstances to ensure that the facility has not routinely "certified" individuals as requiring more supervision as a means of justifying the continued use of open wards or nominally partitioned wards. If the medical risk of an individual is so potentially life threatening that the individual requires continuous unobstructed surveillance during sleeping hours to ensure the health and safety of the individual, then the individual's needs indicate that licensed personnel should be present and 24-hour on-duty staffing patterns will be validated by the surveyor. (See also W344, W333, and W183.)
	(4) The facility must provide each client with--	
W417	(i) A separate bed of proper size and height for the convenience of the client;	§483.470(b)(4)(i) FACILITY PRACTICES: Beds are adapted to meet individual needs (not for staff convenience). The individual's preference, chronological age, and physical and medical needs are the determining factors in bed size and height. §483.470(b)(4)(i) PROBES: Is there a pattern of placing adults with physical disabilities in cribs?
W418	(ii) A clean, comfortable, mattress;	

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W419	(iii) Bedding appropriate to the weather and climate; and	§483.470(b)(4)(iii) GUIDELINES: A single bedspread may be used year round, if it is appropriate for all seasons.
W420	(iv) Functional furniture, appropriate to the clients needs,	§483.470(b)(4)(iv) FACILITY PRACTICES: Individuals with physical disabilities who live in the room are able to use the furniture. Individual preferences and program needs are considered in furniture selection.
W421	and individual closet space in the client's bedroom with clothes racks and shelves accessible to the client.	§483.470(b)(4)(iv) FACILITY PRACTICES: Closets have enough space for a reasonable amount of the current season's clothing. Individuals who use wheelchairs or have other physical challenges can reach the racks and shelves in their closets. §483.470(b)(4)(iv) GUIDELINES: "Furniture" is to be distinguished from "furnishings" (such as plants, pictures, etc.), which though encouraged as being an appropriate and desirable aspect of a normalized living environment, cannot serve as a substitute for appropriate individual furniture that can be used by the individual alone. The facility is permitted either to provide the individual with an individualized closet or with a designated area in a shared closet. The use of central clothing bins in a facility clothing room, in the absence of required individual closet space in the bedroom, is not an acceptable practice.
	(c) Standard: Storage space in bedrooms.	
	The facility must provide--	
W422	(1) Space for equipment for daily out-of-bed activity for all clients who are not yet mobile, except those who have a short-term illness or those few clients for whom out-of-bed activity is a threat to health and safety; and	§483.470(c)(1) FACILITY PRACTICES: There is sufficient space in the bedroom to permit use of wheelchairs, walkers and other adaptive equipment as indicated by the needs of those living in the room.
W423	(2) Suitable storage space, accessible to clients, for personal possessions, such as TVs, radios, prosthetic equipment and clothing.	§483.470(c)(2) FACILITY PRACTICES: There is enough storage space for a reasonable amount of personal possessions. Individuals who use wheelchairs or have other physical challenges can reach and use their own storage space.

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		In the presence of an individual's personal storage space being locked by staff, the individual's program plan documents the necessity for limited access to his/her own possessions and includes provisions to teach the individual the necessary responsible behaviors. §483.470(c)(2) GUIDELINES: For a storage space to be determined as "suitable," it must assure the safekeeping of the individual's possessions among other things being stored. Use of the term "accessible" does not require unrestricted access in situations where this is precluded by an active treatment program designed to eliminate inappropriate behavior, or in which the individual's interdisciplinary team determines that unrestricted access would endanger the individual or others. The surveyor should determine whether or not there is a pattern of restricted access not because of the behavior of the individual, but because of the behavior of others with whom the individual lives. This could also raise the question of inappropriate grouping of individuals due to different functioning abilities.
	(d) Standard: Client bathrooms. The facility must--	
W424	(1) Provide toilet and bathing facilities appropriate in number, size, and design to meet the needs of the clients;	§483.470(d)(1) FACILITY PRACTICES: Bathrooms and fixtures are adapted to accommodate individuals with physical challenges. There are enough bathrooms so that individuals do not have a prolonged wait to use them. §483.470(d)(1) GUIDELINES: "Bathing facilities appropriate in . . . design" must include provisions for a mirror and sink/toothbrushing area.
W425	(2) Provide for individual privacy in toilets, bathtubs, and showers; and	§483.470(d)(2) FACILITY PRACTICES: In a bathroom containing multiple toilets, showers or bathtubs, there are doors, curtains or some other means of protecting the individual from view when fully or partially unclothed. Individuals using bathrooms cannot be seen when passing by the door or window. §483.470(d)(2) GUIDELINES: Gang showers and open toilets are inappropriate to the quality of life, privacy, and personal dignity of the individuals served in the facility. Individual privacy does not preclude the assistance provided by facility staff, when necessitated by the individual's condition.

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W426	(3) In areas of the facility where clients who have not been trained to regulate water temperature are exposed to hot water, ensure that the temperature of the water does not exceed 110° Fahrenheit.	§483.470(d)(3) GUIDELINES: Individuals must be under the direct supervision of staff while being trained to operate hot water temperature controls. §483.470(d)(3) PROBES: If water is above 110 degrees F, do individuals demonstrate ability to self regulate water temperature? Is there a pattern of excluding individuals from the opportunity to learn how to regulate water temperature?
	(e) Standard: Heating and ventilation.	
	(1) Each client bedroom in the facility must have--	
W427	(i) At least one window to the outside; and	§483.470(e)(1)(i) GUIDELINES: Since a door serves primarily to provide egress rather than to perform the ventilation and aesthetic functions of an outside window, it may not be used for room ventilation in place of a window.
W428	(ii) Direct outside ventilation by means of windows, air conditioning, or mechanical ventilation.	§483.470(e)(1)(ii) PROBES: How is ventilation provided? How does the facility regulate room temperatures and ventilation? Is there proper ventilation in individual bathrooms and shower areas?
	(2) The facility must--	
W429	(i) Maintain the temperature and humidity within a normal comfort range by heating, air conditioning or other means; and	§483.470(e)(2)(i) FACILITY PRACTICES: Individuals report that the temperature is comfortable under most circumstances. In extremely hot or extremely cold weather, precautions are taken by the facility to protect the individuals, particularly those who are medically compromised, from ill effects of the temperature. §483.470(e)(2)(i) GUIDELINES: A "normal comfort range" in most instances is defined as not going below a temperature of 68° F or exceeding a temperature of 81 degrees F for facilities in most geographic areas of the country (primarily at the Northernmost latitudes) where that temperature is exceeded only during rare, brief episodes of unseasonably hot weather. §483.470(e)(2)(i) PROBES: How often do temperatures depart from normal comfort ranges?

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		What does the facility do to accommodate temperature to meet individual needs? Are temperature ranges responsive to age or other special conditions or needs of individuals? When equipment failures occur, does the facility attempt to have repairs made as soon as possible?
W430	(ii) Ensure that the heating apparatus does not constitute a burn or smoke hazard to clients.	
	(f) Standard: Floors.	
	The facility must have--	
W431	(1) Floors that have a resilient, nonabrasive, and slip-resistant surface.	§483.470(f)(1) GUIDELINES: "Slip-resistant" is to be distinguished from "slip-free." There is a presumption made that floors will ordinarily be dry, and when wet, appropriate precautions will be taken.
W432	(2) Nonabrasive carpeting, if the area used by clients is carpeted and serves clients who lie on the floor or ambulate with parts of their bodies, other than feet, touching the floor; and	
	(3) Exposed floor surfaces and floor coverings that	
W433	promote mobility in areas used by clients,	
W434	and promote maintenance of sanitary conditions.	
	(g) Standard: Space and equipment.	
	The facility must--	

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W435	(1) Provide sufficient space and equipment in dining, living, health services, recreation, and program areas (including adequately equipped and sound treated areas for hearing and other evaluations if they are conducted in the facility) to enable staff to provide clients with needed services as required by this subpart and as identified in each client's individual program plan.	§483.470(g)(1) FACILITY PRACTICES: Staff and individuals have the space, materials and equipment needed for the formal and informal active treatment program to be carried out. There is sufficient space to accommodate group activities, including groups with individuals who use wheelchairs. Recreational supplies and materials are available and reflect the interests, abilities and chronological age of the individuals. §483.470(g)(1) PROBES: Is there sufficient space and adaptive equipment so that individuals in wheelchairs can go outside regularly and participate in recreational events?
W436	(2) Furnish, maintain in good repair, and teach clients to use and to make informed choices about the use of dentures, eyeglasses, hearing and other communications aids, braces, and other devices identified by the interdisciplinary team as needed by the client.	§483.470(g)(2) FACILITY PRACTICES: Individuals in need of adaptive/assistive/supportive/prosthetic equipment specified by the IDT are observed to have them and are taught to use and care for this equipment to the extent of their capabilities. Individuals are observed using braces, mobility aids, positioning devices, and other adaptive equipment which meet their needs and increase functionality. Equipment is observed to be in good repair. §483.470(g)(2) GUIDELINES: The term "furnish" means that the facility is responsible for obtaining or purchasing these items and is responsible for making any necessary arrangements to enable the individual actually to receive them. However, if an item is available free of charge the facility would satisfy the requirement simply by making the necessary arrangements for the individual to receive them. Individuals' personal funds should not be used for these items since this is a covered service under the ICF/MR benefit. The term "maintain in good repair" means that the facility is responsible for ensuring that these items are kept in good working order. §483.470(g)(2) PROBES: What provisions are made for repairs of protheses and assistive technology devices? Are repairs timely? Are needed protheses and assistive technology devices in good repair and proper fit? Are loaners available during repair periods? How does the facility address the use of special devices with individuals who are resistive of their use?
W437	(3) Provide adequate clean linen and dirty linen storage areas.	§483.470(g)(3) FACILITY PRACTICES: Clean linen is separated from dirty linen.

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		Clean linen is stored in a manner which prevents contamination. Linen soiled with bodily fluids is stored in a manner which protects individuals from exposure to possible infectious sources. §483.470(g)(3) GUIDELINES: A bedroom hamper can be an acceptable dirty linen storage "area" if kept odor free, consistent with the infection control requirements at §483.470(1).
	(h) Standard: Emergency plan and procedures.	
W438	(1) The facility must develop and implement detailed written plans and procedures to meet all potential emergencies and disasters such as fire, severe weather, and missing clients.	§483.470(h)(1) FACILITY PRACTICES: Emergency plans exist. Emergency plans address those types of emergencies relevant to the facility, its geographic location and the needs of the individuals served. Staff follow emergency procedures both during drills and in real emergencies.
W439	(2) The facility must communicate, periodically review, make the plan available, and provide training to the staff.	§483.470(h)(2) FACILITY PRACTICES: Staff know where emergency plans and procedures are located. Staff report training in emergency procedures. Emergency plans have been updated if conditions affecting them have changed. §483.470(h)(2) GUIDELINES: "Periodic review" is a judgment made by the facility based on the circumstances of the facility. If the facility changes its physical plant or if changes external to the facility necessitates a review of the disaster plan, then the facility is responsible for carrying out the review.
	(i) Standard: Evacuation drills.	
	(1) The facility must hold evacuation drills	
W440	at least quarterly for each shift of personnel	§483.470(i)(1) FACILITY PRACTICES: Each shift has participated in an evacuation drill at least once in a 3-month period.
W441	and under varied conditions to--	§483.470(i)(1) FACILITY PRACTICES: Staff, and individuals who are being trained/assisted/supported to evacuate on their own, practice evacuating at different times of the day and night, from different rooms in the facility, using different escape routes and in various weather conditions.

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W442	(i) Ensure that all personnel on all shifts are trained to perform assigned tasks;	§483.470(i)(1)(i) FACILITY PRACTICES: All staff know what they are to do in an emergency.
W443	(ii) Ensure that all personnel on all shifts are familiar with the use of the facility's fire protection features; and	§483.470(i)(1)(ii) FACILITY PRACTICES: Staff know how to use fire extinguisher, alarms, and any other safety features in the facility.
W444	(iii) Evaluate the effectiveness of emergency and disaster plans and procedures.	§483.470(i)(1)(iii) FACILITY PRACTICES: The facility determines whether the plans and procedures are adequate.
	(2) The facility must--	
W445	(i) Actually evacuate clients during at least one drill each year on each shift;	§483.470(i)(2)(i) FACILITY PRACTICES: All individuals totally evacuate the building at least once per year per shift, regardless of the occupancy chapter under which the building falls. §483.470(i)(2)(i) GUIDELINES: All facilities, regardless of their size require actual evacuation. "Actually evacuate," as used in this standard, applies to all individuals. The drills are conducted not only to rehearse the individuals and staff for fire (see §483.470(i)(2)(v)), but for other disasters such as hurricanes, tornadoes, floods, etc. Such disasters would require the entire occupancy to be evacuated, and, therefore, the actual evacuation must be practiced, as required.
W446	(ii) Make special provisions for the evacuation of clients with physical disabilities;	§483.470(i)(2)(ii) FACILITY PRACTICES: Individuals with physical disabilities can be evacuated.
W447	(iii) File a report and evaluation on each evacuation drill;	§483.470(i)(2)(iii) PROBES: What problems and corrective actions do fire drill reports identify?
W448	(iv) Investigate all problems with evacuation drills, including accidents,	
W449	and take corrective action; and	§483.470(i)(1)(iii) FACILITY PRACTICES: When a problem is identified in evacuating, the facility takes steps which are reasonably likely to correct the problem.

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W450	(v) During fire drills, clients may be evacuated to a safe area in facilities certified under the Health Care Occupancies Chapter of the Life Safety Code.	
W451	(3) Facilities must meet the requirements of paragraph (i)(1) and (2) of this section for any live-in and relief staff they utilize.	§483.470(i)(3) GUIDELINES: Since live-in staff and their relief personnel are generally the same staff who work with the individuals on a round-the-clock basis, they must conduct a minimum of 4 drills a year, each of which must occur at different times within the day (24-hour period) (i.e., morning, afternoon, and night (sleep time)), and generally when individuals are at different locations within the house. If the facility has large numbers of relief personnel, more drills may be needed to meet the intent of this requirement.
	(j) Standard: Fire protection.	§483.470(j) GUIDELINES: These standards are covered by the Life Safety Code (LSC) survey. The facility must meet the appropriate chapter of the Life Safety Code, 1985 edition. §483.470(j) SURVEY PROCEDURES: When surveying an ICF/MR for compliance with the LSC, it is first necessary to determine whether the facility will be surveyed under Health Care (HC) or Board and Care (BC) occupancy. o If individuals receive nursing services, or if the provider elects to use Health Care, the facility should be surveyed as a Health Care Facility under Chapter 12 or 13 of the LSC, as appropriate. o If individuals receive personal care and protective oversight but not chronic nursing services, the facility is to be surveyed under Board and Care and the following three steps should be followed: 1. Determine the size (16 or less = small; 17 or more = large); 2. Determine the Evacuation Difficulty (PROMPT, SLOW, or IMPRACTICAL) using Appendix F of the fire safety evaluation system for board and care facilities (FSES/BC); and 3. Survey the building using one of two methods: a. The prescriptive requirements of Chapter 21; or b. The FSES/BC, Appendix G. If the FSES/BC is used, validate the rating of individuals as part of the sampling process. If significant discrepancies are noted from what staff report and what evidence can be ascertained about individual behavior, conduct an indepth investigation into the ratings of all individuals in conjunction with the LSC surveyor.
	(1) General. (i) Except as specified in paragraph (j)(2) of this section, the facility must meet the applicable provisions of either the Health Care Occupancies Chapters or the Residential Board and Care Occupancies Chapter of the Life Safety Code (LSC) of the National Fire Protection Association, 1985 edition, which is incorporated by reference.	
	(ii) The State survey agency may apply a single chapter of the LSC to the entire facility or may apply different chapters to different buildings or parts of buildings as permitted by the LSC.	
	(iii) A facility that meets the LSC definition of a residential board and care occupancy and that has 16 or fewer beds, must have its evacuation capability evaluated in accordance with the Evacuation Difficulty Index of the LSC (Appendix F).	

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	(2) Exceptions (i): For facilities that meet the LSC definition of a health care occupancy:	
	(A) The State survey agency may waive, for a period it considers appropriate, specific provisions of the LSC if-- (1) The waiver would not adversely affect the health and safety of the clients; and (2) Rigid application of specific provisions would result in an unreasonable hardship for the facility.	
	(B) The State survey agency may apply the State's fire and safety code instead of the LSC if the Secretary finds that the State has a code imposed by State law that adequately protects a facility's clients. (C) Compliance on November 26, 1982 with the 1967 edition of the LSC or compliance on April 18, 1986 with the 1981 edition of the LSC, with or without waivers, is considered to be in compliance with this standard as long as the facility continues to remain in compliance with that edition of the Code.	
	(ii) for facilities that meet the LSC definition of a residential board and care occupancy and that have more than 16 beds, the State survey agency may apply the State's fire and safety code as specified in paragraph (j)(2)(B) of this section.	
	(k) Standard: Paint.	

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	The facility must--	
W452	(1) Use lead-free paint inside the facility; and	
W453	(2) Remove or cover interior paint or plaster containing lead so that it is not accessible to clients.	
	(l) Standard: Infection Control.	
W454	(l) The facility must provide a sanitary environment to avoid sources and transmission of infections.	§483.470(l)(1) FACILITY PRACTICES: Individuals do not have access to soiled diapers, linens, bandages or any other potentially infectious material. These materials are handled in a manner which prevents leakage from containers or exposure to the general environment. Bathroom fixtures and surfaces are free from bodily wastes. Kitchen counters are cleaned at appropriate times during food preparation.
W455	There must be an active program for the prevention, control, and investigation of infection and communicable diseases.	§483.470(l)(1) FACILITY PRACTICES: Staff are observed washing hands, when appropriate. Individuals are trained and encouraged to maintain good hygiene practices. Staff follow Center for Disease Control (CDC) guidelines for universal precautions. §483.470(1)(1) GUIDELINES: An "active program" includes such observable practices as: the direct care staff routinely washing their hands or changing gloves after working with an individual who has an infectious disease or working with each individual during mealtimes; the use of aseptic technique, when appropriate; an ongoing program of communicable disease control and investigation of infections; and an active training program that ensures the individuals served receive adequate prevention of transmission information and skills, according to needs. Procedures must be followed to prevent cross-contamination, including hand washing or changing gloves at mealtimes, after providing personal care to more than one individual, or when performing other tasks among individuals which provide the opportunity for cross-contamination to occur. Facilities for hand washing must exist and be available to staff. Toothbrushes and other personal hygiene items must be stored and used in such a manner to prevent cross-contamination.

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		Both the OSHA and the CDC have specific requirements regarding human immuno-deficiency virus (HIV), TB, and hepatitis precautions. These requirements should be incorporated into the facility's practices when relevant to the individuals residing in the facility. Concerns about OSHA violations should be referred to OSHA.
W456	(2) The facility must implement successful corrective action in affected problem areas.	§483.470(1)(2) PROBES: In instances of infection control problems are there patterns to suggest: o Staff are not practicing established techniques? o Problems are not being analyzed to result in corrective action? o There is aggressive resolution to problems identified that leads overall to a reduction in the number of infection control problems? Is there evidence of individuals contracting infections or communicable diseases that can be attributed to poor infection control practices?
W457	(3) The facility must maintain a record of incidents and corrective actions related to infections.	§483.470(l)(3) GUIDELINES: This regulation does not require the recording or tracking of specific groups of symptoms, if a record of incidents and corrective actions related to infections is maintained. This regulation does not address the form or location of this record or direct that it be separate from the documentation required by CFR 483.410(c)(1).
W458	(4) The facility must prohibit employees with symptoms or signs of a communicable disease from direct contact with clients and their food.	§483.470(l)(4) FACILITY PRACTICES: Staff who have an illness or communicable disease that can be transmitted through direct contact with individuals or indirectly through their food, are not observed working with either. §483.470(1)(4) GUIDELINES: The facility should use the Recommendations for Prevention of Communicable Disease Transmission in Health Care Settings (such as preventing HIV) issued by the Centers for Disease Control, Atlanta, Georgia 30333, as well as OSHA guidelines in these areas. A facility participating in the Medicaid program may not discriminate against individuals who are HIV-infected so long as these individuals do not (on a case-by-case basis) pose a substantial health and safety risk to others, or pose a performance problem, and are "otherwise qualified."

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W459	§483.480 Condition of participation: Dietetic services.	§483.480 COMPLIANCE PRINCIPLES: The Condition of Participation of Dietary Services is met when: o The individuals maintain body weights and lab levels considered acceptable for their age, height, body type and clinical condition or are receiving services and supports to assist them to do so; and o Individuals participate in normalized dining experiences appropriate to their functional abilities (e.g., using knives, family style meals, going to restaurants, etc.) and are being taught skills to do so. The Condition of Participation of Dietary Services is not met when: o Individuals experience excessive weight loss or gain, abnormal lab levels, or deterioration in health as a result of an inadequate diet; or o Individuals do not receive training and supports which enable them to eat as independently and in as normalized manner as possible.
	(a) Standard: Food and nutrition services.	
W460	(1) Each client must receive a nourishing, well-balanced diet including modified and specially-prescribed diets.	§483.480(a)(1) FACILITY PRACTICES: Individuals are receiving adequate nutrition as indicated by: o Maintaining body weights considered to be acceptable for their age, height and body type; o Laboratory studies show values within normal ranges; o Medical problems are not related to the facility's failure to provide adequate nutrition; o Food allergies are recognized and the person does not receive foods to which (s)he is allergic; o Substitutions made for planned menu items are of similar nutritive value; and o Diets are changed in response to identified nutritional deficiencies. The individual's unmet nutritional needs are known to the facility and are being addressed. §483.480(a)(1) GUIDELINES: "Modified and specially-prescribed" diets are defined as diets that are altered in any way to enable the individual to eat (for example, food that is chopped, pureed, etc.) or diets that are intended to correct or prevent a nutritional deficiency or health problem. §483.480(a)(1) PROBES: Within the context of the characteristics of the individuals who reside in the facility, is there a pattern of excessive usage of "food allergy," weight gain and/or reduction diets which may indicate an unnecessary and non-normalizing emphasis on special diets? When food consistency modifications are necessary, is there evidence of periodic efforts to upgrade the food consistency for individuals?

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		Are weight reduction diets generally coordinated with plans for exercise? Is the diet order followed as prescribed? Are between meal snacks provided as needed? Are desired weight range goals maintained or supported with the calories and nutrients provided? What evidence is there to support that the diet is being implemented? How does the facility assure that menus are nutritionally adequate and varied? Is there clinical evidence that supports observation of compromised nutritional status: o Recent significant weight gain or loss? o Fever/infection? o Diarrhea? o Chronic disease? o Chewing and swallowing problems? o Chronic blood loss? o Teeth and gum diseases? o Excessive use of laxatives? o Abnormal laboratory values? Are the staff aware of and do they respond to any potential adverse food/drug interactions? Have individuals on long term anticonvulsant drug regimens (e.g., phenobarbital, phenytoin, primidone) been monitored for decreased serum levels of folic acid and vitamin D? Have therapeutic doses of affected nutrients been provided to decrease the likelihood of megaloblastic anemia and decreased bone density? If not, why? Have fiber and fluids been increased in the diet of individuals on anticonvulsants and tranquilizers to decrease likelihood of constipation? If not, why?
W461	(2) A qualified dietitian must be employed either full-time, part-time, or on a consultant basis at the facility's discretion.	
W462	(3) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food services.	

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	(4) The client's interdisciplinary team, including a qualified dietitian and physician must prescribe	
W463	all modified and special diets	§483.480(a)(4) FACILITY PRACTICES: The IDT, including the dietician and physician, have reviewed the individual preferences and attitudes about food and his/her nutritional and health status as a basis for prescription of the individual's diet. §483.480(a)(4) PROBES: Is the dietitian involved in reviewing information about individuals and gathering additional information, such as laboratory reports and drugs prescribed, that might affect food intake? Have the modified and special diet orders been reviewed for their appropriateness and effectiveness? How has the individual's response to the diet been considered?
W464	including those used as a part of a program to manage inappropriate client behavior.	§483.480(a)(4) FACILITY PRACTICES: When a special diet is to be used as part of a behavior management program, it has been reviewed for appropriateness, taking the individual's response to the diet into account.
W465	(5) Foods proposed for use as a primary reinforcement of adaptive behavior are evaluated in light of the client's nutritional status and needs.	§483.480(a)(5) GUIDELINES: Since the main purpose of food is to support and maintain the health of an individual, it is important that the use of food as a behavior reinforcing device (primary reinforcement) not be abused. Foods are selected to provide essential nutrients. When these foods are routinely removed and denied during the meals, without comparable replacements, the individual is at risk of consuming a diet that is not adequate to meet nutritional needs, and in violation of §483.420(d)(1)(ii), which does not allow food contributing to a nutritionally adequate diet to be used as "punishment." Likewise, the addition of high caloric reinforcers must be coordinated into the total daily diet intake. §483.480(a)(5) PROBES: If food is withheld during a meal, is food of comparable nutritive value to the withheld menu item provided? Are the primary reinforcers used with individuals consistent with the diet intended for those individuals? Are the types of food used as primary reinforcers consistent with other IPP objectives or needs (e.g., if the individual is learning to use finger foods, are "finger food" types of reinforcers (like grapes) used?) Refer to W151.

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W466	(6) Unless otherwise specified by medical needs, the diet must be prepared at least in accordance with the latest edition of the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, adjusted for age, sex, disability and activity.	§483.480(a)(6) GUIDELINES: For suggested guidelines write to: 1. U.S. Department of Agriculture Human Nutrition Information Services Washington, D.C. 20250 2. The National Dairy Council Rosemont, Illinois 60028-42334
	(b) Standard: Meal services.	
W467	(1) Each client must receive at least three meals daily,	§483.480(b)(1) GUIDELINES: It is the facility's responsibility to ensure that meals eaten regularly outside the facility are adequate (e.g., that an individual at a community program setting has an adequate lunch carried from the facility or is able to purchase lunch). There is a concern that individuals may consume only "junk" food instead of an adequate meal when outside the facility.
W468	at regular times comparable to normal mealtimes in the community	§483.480(b)(1) FACILITY PRACTICES: The scheduling of meals is flexible and not overly rigid. Mealtimes accommodate a variety of recreational activities (in and out of the facility) throughout the year, especially weekend and holiday activities. §483.480(B)(1) PROBES: Are mealtimes, including snack times, sufficiently flexible to allow the individual opportunities to participate in a variety of activities in and out of the facility? Are snacks consistent with the individual's intended diet? Are snacks routinely provided to all individuals?
	with--	
W469	(i) Not more than 14 hours between a substantial evening meal and breakfast of the following day,	§483.480(b)(l)(i) GUIDELINES: A "substantial evening meal" is defined as offering of three or more menu items at one time, one of which includes a high-quality protein such as meat, fish, eggs, or cheese. The meal represents no less than 20% of the day's total nutritional requirements.

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W470	except on weekends and holidays when a nourishing snack is provided at bedtime, 16 hours may lapse between a substantial evening meal and breakfast; and	§483.480(b)(1)(i) GUIDELINES: A "nourishing snack" is an offering of items, single or in combination, from the daily food guide.
W471	(ii) Not less than 10 hours between breakfast and the evening meal of the same day, except as provided under paragraph (b)(1)(i).	
	(2) Food must be served--	§483.480(b)(2)(i) FACILITY PRACTICES: Portions served, either by staff or by the individuals themselves, closely match designated serving sizes on menus. Slight variations are not significant enough or frequent enough to affect individual's health.
W472	(i) In appropriate quantity;	
W473	(ii) At appropriate temperature;	§483.480(b)(2)(ii) FACILITY PRACTICES: Hot and cold foods are served promptly, i.e., within 15 minutes of removal from temperature control devices. When situations arise which prevent food from being maintained at proper temperatures, or prevent food from being served promptly upon removal from temperature control devices, that food is not served to individuals residing in the facility. §483.480(b)(2)(ii) PROBES: Are hot foods held at not less than 140 degrees F. and served promptly (i.e., within 15 minutes of being removed from temperature control devices)? Are cold foods held and served at 45 degrees F.? Do you observe individuals eating within 15 minutes from the time of service (time the food was taken out of temperature control devices)? Is there a pattern of food-related illnesses, resulting from inappropriate temperature control?
W474	(iii) In a form consistent with the developmental level of the client; and	§483.480(b)(2)(iii) FACILITY PRACTICES: The individual receives food that is ground, chopped or pureed, based on individual need, and only to the extent required.

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		§483.480(b)(2)(iii) GUIDELINES: The term "form," as used in this requirement, refers to food consistency (i.e., pureed, chopped, ground, etc.) §483.480(b)(2)(iii) PROBES: On what basis does the facility decide to modify the texture of an individual's diet? Is there specific justification for a pureed diet? When food consistency modifications are necessary, is there evidence of periodic efforts to upgrade the food consistency for individuals? Are foods sufficiently moist for ease of chewing and swallowing? Is pureed food of a consistency that is appropriate for the individual's eating and swallowing ability and not in liquid ("watery") consistency? For individuals who have great physical difficulty in eating and swallowing, and must be fed: o Do staff use appropriate swallowing stimulation techniques? o Proper tongue thrust reduction techniques? o Do staff use proper food and liquid thickening agents to facilitate easier eating and swallowing? o Are pureed foods mixed with other foods and fed to individuals? Or do individuals get to enjoy the tastes of various foods separately fed to them? o Is the food positioned so that the individual is permitted to see his or her meal? o Is the individual positioned appropriately?
W475	(iv) With appropriate utensils.	§483.480(b)(3) FACILITY PRACTICES: Common serving utensils are in good condition, clean, and yield portion sizes appropriate to the individual's prescribed diet.
W476	(3) Food served to clients individually and uneaten must be discarded.	§483.480(b)(3) GUIDELINES: This standard does not apply to food served in family-style dishes, unless the length of time the food is on the table or other considerations (such as individuals fingering or drooling in the food) compromise the safety and nutritive value for reuse of the food. §483.480(d)(3) PROBES: Is food remaining on the individual's dishes saved or reused after the meal is completed?
	(c) Standard: Menus.	

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	(1) Menus must--	
W477	(i) Be prepared in advance;	§483.480(c)(1)(i) PROBES: Are menus available for those individuals who can read?
W478	(ii) Provide a variety of foods at each meal;	§483.480(c)(1)(II) PROBES: Do individuals participate in the selection of menu items, to the maximum extent possible? Are substitutions made within the same food group, i.e., meat for another source of protein? Vegetable for another item similar in nutritional value? Are individuals allowed to substitute menu items with their own choices (even though seemingly void in variety (e.g., an individual wishes to consume pizza 3 times per week, or on consecutive days) provided that the items contain the nutritive value comparable to the planned items on the menu? Do menus specify the "name" of the juice, vegetable, or starch (i.e., orange juice, green beans, rice)?
W479	(iii) Be different for the same days of each week and adjusted for seasonal changes; and	§483.480(c)(1)(iii) PROBES: Do menus reflect variety for the season of the year (e.g., fresh fruits in summer)?
W480	(iv) Include the average portion sizes for menu items.	§483.480(c)(1)(iv) PROBES: Is there evidence that sufficient food exists to yield the portion sizes indicated on the menu?
W481	(2) Menus for food actually served must be kept on file for 30 days.	§483.480(c)(2) PROBES: Are substitutions noted when intended menu items are not served?
	(d) Standard: Dining areas and service.	
	The facility must--	
W482	(1) Serve meals for all clients, including persons with ambulation deficits, in dining areas, unless otherwise specified by the interdisciplinary team or a physician;	§483.480(d)(1) FACILITY PRACTICES: If an individual does not eat in the dining area, the physician has documented the medical necessity for, and/or the IPP documents the plan to teach the individual the physical and/or other skills necessary for inclusion. Individuals are not precluded from eating in the dining room solely based on diagnosis or level of functioning. §483.480(d)(1) GUIDELINES: For purposes of this standard "dining areas" mean discrete eating areas located outside

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		of bedrooms, established, furnished, and equipped for the purpose of eating meals. For purposes of this standard, provision of meals in dining areas outside of the home (such as restaurants, food vendors, etc.) may also be included. To the maximum extent possible, individuals should be afforded the opportunity to eat routine meals (like breakfast and dinner) in dining areas that approximate those afforded to their peers without disabilities (e.g., dining areas that are a part of the living unit, rather than eating all meals in buildings exclusively established for eating purposes). §483.480(d)(1) PROBES: Is the dining room a pleasant environment in which to eat? Is there a pattern of individuals eating their meals in their bedrooms, or other non-eating areas? What is the rationale for prohibiting an individual from eating in a dining area? Has eating in a dining area ever been tried with the individual before? What happened? Are periodic attempts to get such individuals to eat in a dining area, continued?
W483	(2) Provide table service for all clients who can and will eat at a table, including clients in wheelchairs;	§483.480(d)(2) GUIDELINES: The intent of this regulation is to afford individuals the opportunity to participate in the social experience of dining with their companions. Observe whether or not facility staff model and reinforce appropriate communication and social behavior between dining companions seated at the same table. §483.480(d)(2) PROBES: Do individuals eat together with others at the same table? Are individuals in wheelchairs positioned correctly and included in dining groupings of their peers without physical disabilities? Or do all individuals in wheelchairs eat together or are they located around the edges of dining areas? Are individuals in wheelchairs lined-up to eat? Do individuals in wheelchairs routinely eat at table? or do they eat on their lap trays or hospital bed trays? On what basis does the facility determine if an individual in a wheelchair needs to eat the meal in the wheelchair rather than transferring to a regular chair?
W484	(3) Equip areas with tables, chairs, eating utensils, and dishes designed to meet the developmental needs of each client;	§483.480(d)(3) FACILITY PRACTICES: Individuals are provided with adapted furniture and equipment as identified by the IDT at each meal. Individuals use adaptive equipment or are being trained to use it when needed. §483.480(d)(3) GUIDELINES: Single service eating devices must be discarded after each use.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		Determine if the following types of adaptive devices are made available when needed: 1. Double suction cups or other devices to anchor dishes on a table or tray for individuals with major coordination problems; 2. Rocking one-handed knife-fork or knife-spoon for an individual with the use of only one hand; 3. Built up or extended handles or silverware for those with problems of grasp or range of motion; 4. Plate guards or plates with raised rims to provide a surface against which the individual with a physical disability can push food onto a fork or a spoon; 5. Flexible drinking straws; 6. Spoon bent to a 90 degree angle at the bowl or a swivel spoon to assist an individual without normal wrist motions. 7. Any other adaptive device deemed by the team as needed by the individual to eat more independently. §483.480(d)(3) PROBES: Are condiments, napkins and appropriate eating utensils provided? Are individuals trained to use them? Is there a pattern of staff allowing individuals to use any piece of adapted equipment, regardless of the individual's need for that equipment? Is the height of the dining table sufficient so that an individual in a wheelchair can sit in the wheelchair at the table, if needed?
W485	(4) Supervise and staff dining rooms adequately	§483.480(d)(4) FACILITY PRACTICES: There are sufficient staff to implement eating programs for individuals who require them and to provide necessary supervision.
W486	to direct self-help dining procedures,	§483.480(d)(4) FACILITY PRACTICES: Staff monitor individuals who are able to dine independently in order to promote, support, reinforce and encourage individuals to eat in an appropriate and normalized manner (e.g., manners, social behaviors, etc.)
W487	to assure that each client receives enough food and	§483.480(d)(4) FACILITY PRACTICES: As indicated by the nutritional assessment and prescribed diet, individuals can access second helpings.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		For individuals who have significant spillage or refuse foods, diets are adjusted as needed. Individuals have enough time to finish their full meal.
W488	to assure that each client eats in a manner consistent with his or her developmental level; and	§483.480(d)(4) FACILITY PRACTICES: Individuals are actively encouraged to feed themselves to the extent possible and in accordance with their assessed abilities. Individuals learn skills in accordance with their functional levels including: o Use of utensils; o Meal preparation; o Socialization during meals; o Family style dining; and o Ordering food in restaurants. Individuals' eating programs are implemented in accordance with their training objectives. §483.480(d)(4) GUIDELINES: To the maximum extent possible, staff should model appropriate mealtime behavior and conversation by sitting at the table with individuals, and, when possible, eating meals with individuals. Mastery of the social skills involved in eating in a variety of dining areas and settings is another step to the individual's independence beyond the health aspects of nutrition and the basic skills involved in eating independently. Achieving independence will further help the individual to live in less restrictive environments. Determine to what extent individuals are exposed to out-of-the-home dining environments available to the general public (e.g., restaurants, fast-food establishments, picnics, parties, cafeterias, etc.) Depending on the needs of the individuals and the available space it may be more effective for meals to be conducted in two different seatings or groupings. §483.480(d)(4) PROBES: Is the individual encouraged, permitted and reinforced for being as independent as possible during meals? Do staff demonstrate skills and techniques which promote socialization? Do facility staff enable individuals who are eating dependent, when appropriate, to move from tube-feeding, or blended, ground, pureed, etc., to the next level of food size, texture, or otherwise greater levels of independent eating? How does staff address the problem of individuals who consistently show a lack of interest in eating?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		Is family style dining made available to individuals who are able to participate? Are individuals allowed to dine out at places like fast food restaurants, buffets, vendors at the park or beach? How do staff deal with individuals who exhibit maladaptive behavior during mealtime? Is it part of the individual's IPP? Are individuals rushed through their meals? Is there a pattern of eating programs not being implemented on short staffed days? short staffed meals? In the presence of staff? Is the food to be eaten, located at a distance and level from the individual, such that the individual can eat with maximum independence? Is the individual taught to use the most normal, least stigmatizing clothing protectors during mealtimes? Do individuals take turns participating in setting their own tables? Serving their own meals? Preparing meals? Shopping for and putting food away?
	(5) Ensure that each client eats in an upright position, unless otherwise specified by the interdisciplinary team or a physician.	§483.480(d)(5) FACILITY PRACTICES: Individuals are positioned appropriately for eating. If an individual eats in a reclining position, the physician documents the medical necessity for the position, and/or the IPP includes the program plan to teach the individual the physical skill necessary for eating upright. §483.480(d)(5) GUIDELINES: This applies to all individuals, including those fed by nasogastric tube or gastrostomy tube. The IPP should identify the most appropriate position for the individual to be positioned during mealtime, in relation to the placement of the food contents. §483.480(d)(5) PROBES: For individuals who have great physical difficulty in eating or swallowing and must be fed, is the individual positioned in the upright position appropriate to the individual's needs?

APPENDIX K
COMPREHENSIVE OUTPATIENT REHABILITATION FACILITIES
INTEPRETIVE GUIDELINES

APPENDIX K

INTERPRETIVE GUIDELINES
Comprehensive Outpatient Rehabilitation Facilities

Conditions of Participation

Explanation of Conditions of Participation for
Comprehensive Outpatient Rehabilitation Facilities

I. COMPLIANCE WITH STATE AND LOCAL LAWS (42 CFR 488.54)

A. General.--In order to assure that the Comprehensive Outpatient Rehabilitation Facilities (CORF) and staff furnishing services are in possession of current licenses as required by State and local laws, licenses should be available for review. Compliance with this condition may have a bearing on other conditions; e.g., comprehensive rehabilitation program (42 CFR 488.58) and physical environment (42 CFR 488.62).

B. Major Sources of Information

l. State and local laws governing health care; building, fire and safety codes;

2. Applicable State and local licenses and organization personnel records containing up-to-date information; and

3. Written policies pertaining to communicable and reportable diseases, conforming to applicable State and local laws.

C. Standards

Standard (a): Licensure of Facility.--Ascertain that all State and local licenses, permits and approvals which govern the facility's operation are current and valid. The facility must meet all building, fire and safety codes where these are required for licensure before a facility would be eligible for certification. If the proper authorization(s) has not been granted, or has been temporarily revoked or suspended, the facility should be found in noncompliance with this standard, Condition I, Compliance with State and local laws (§488.54) should be marked not met and the facility should be refused admission into the program or termination proceedings should be initiated, whichever is appropriate.

If a facility has been issued a provisional license, permit or approval, document the reason for this issuance including the limitation(s) imposed on the facility's operation. Determine whether the limitation(s) prevents the facility from complying with the conditions of participation. If so, mark the applicable condition(s) and/or standard(s) in accordance with the instructions found in §2300ff.

Facilities exempt from State licensure, must be approved by the State as meeting the standards established for licensure. Examples of exempted facilities may include facilities that operate on a Federal reservation under agreement with the Department of Health and Human Services and facilities operated by a State, city or county health department.

Standard (b): Licensure of Personnel.--Personnel providing services at the CORF must be licensed or registered where applicable. This includes employees, independent contractors and individuals from organizations with which the CORF has an arrangement to provide services. Review a central State listing or other evidence such as wallet size identification cards to verify licensure or registration of personnel.

II. GOVERNING BODY AND ADMINISTRATION (42 CFR 488.56)

A. General.--The CORF must have a governing body which is responsible for its policies and operation, and which appoints an individual to act as the facility administrator. A group of professional personnel must develop and review policies that govern the CORF services.

The governing body is the Board of Directors or Trustees of a corporation or the owner(s), in the case of a proprietary agency or others who assume legal responsibility for the facility. Assess the effectiveness and adequacy of the governing body's management and operation of the facility by reviewing documentation of the governing body's activities. This documentation should include minutes of the governing body, policy statements, bylaws and delegations of authority. While there are no requirements that the governing body follow a prescribed meeting schedule, there should be evidence that the governing body takes an active role in the overall operation of the CORF. This includes the development and review of the institutional budget plan, and knowledge of and concurrence with all patient care and major operational policies. Place the names of governing body members in the space provided.

B. Major Sources of Information

1. Articles of incorporation, bylaws, policy statements, etc.

2. Minutes of governing body, staff and patient care policy meetings

3. Organization chart showing administrative framework

4. Personnel records -- job descriptions and personnel qualifications

5. Institutional budget plan

6. Management contracts

7. Patient care policies

8. Clinical records

C. Standards

Standards (a): Disclosure of Ownership.--The facility must disclose certain information about its ownership and control in complying with 42 CFR Part 420, Subpart C. Review the Ownership and Control Interest Statement, HCFA-l5l3 (Exhibit 6A) carefully for completeness prior to the survey. Instructions for completion are contained on the form. Follow the procedures in Sections 2l30 and 2l40 for obtaining, collecting and reviewing the HCFA-l5l3. Failure on the part of the CORF to fully disclose ownership may result in the withdrawal of eligibility status for program participation or termination of an existing CORF provider agreement.

Standard (b): Administrator.--The governing body must appoint an administrator who has responsibility for the overall management of the facility and retains professional and administrative responsibility for all personnel providing facility services. The qualifications of an administrator may vary among facilities, i.e., some administrators may be health professionals while others may be business managers. The administrator's basic responsibility regardless of the field of expertise, is to assure that services are rendered in accordance with CORF policies and that there is efficient utilization of resources and coordination of services. The administrator should have a thorough working knowledge of the overall operation of the facility, including the scope of services provided, policies governing these services, budgetary and fiscal matters and the utilization and qualification of personnel. Discussion with the administrator will assist in determining depth of facility knowledge.

An administrator, especially of a large facility, generally functions on a full-time basis. However, a small facility may have a part-time administrator, e.g., one who also provides services as one of the professional personnel. Where this is the case, determine if the amount of time the administrator spends performing administrative functions is commensurate with the facility's scope of operations. If it is determined that

administrative functions are suffering, inform the facility that an adjustment of its present system is in order. This adjustment may require that the facility, for example, expand the administrator's hours, or alter its operation so that the administrator is able to more appropriately implement and enforce its policies and procedures. Facility policies must designate in writing an individual who acts on behalf of the administrator during a period of absence. If in a small facility, as noted above, the administrator also provides professional services, an individual to serve during periods when the administrator is not on the CORF's premises should be designated.

Standard (c): Group of Professional Personnel.--The group of professional personnel serves a very specific facility function, that is, to make certain that policies relating to patient care are realistic and best meet the needs of the facility and patients alike. Effective facility operation is dependent, in part, on workable policies especially those relating to: limitation of service capability, criteria for patient admission, etc. These policies must be developed and periodically reviewed by the group of professional personnel. The facility should be able to show that the group of professional personnel is carrying out its policy formulation and review function. The group must consist of at least one physician and one professional representing each of the services provided by the facility. The names of all group members must be available and evidence must confirm their participation in policy development and review. This evidence can be minutes of meetings or other documentation which reflects that this function is being carried out.

All or part of the group of professional personnel, or a group of similar composition, can serve as the facility's utilization review committee (see Condition VII, Standard (a)). Although a similarly comprised group not associated with the facility can perform the utilization review function, it cannot develop and periodically review the facility's policies.

Standard (d): Institutional Budget Plan.--In reviewing the facility's institutional budget plan (i.e., budget and/or a capital expenditure plan), consideration is to be given solely to its presence, and its annual review by the governing body. It is not important how this material is identified, just that it exists. Do not determine specific item appropriateness and do not review for substance.

The budget and/or plan must be prepared under the direction of the governing body by a committee composed of at least one member of the governing body and at least one member of the administrative staff.

The administrative representative is not required to have accounting, planning, or any other specific professional background, but should be in a management position. Documentation should verify that a governing body representative has been designated to work with a representative of the administrative staff.

For purposes of this section, a capital expenditure plan is for at least a three-year period, including the current and the two succeeding fiscal years. The period shown should correspond to the facility's budget fiscal year. A capital expenditure plan is required when an expenditure in excess of $100,000 for this three-year period is expected. The administrator may state that there is no capital expenditure plan because no capital expenditure in excess of $100,000 is anticipated. In this case, the appropriate part of the survey report form should be noted "Not Applicable" and the administrator's reason shown in the Explanatory Statements column.

Included as part of capital expenditures are the costs related to studies, surveys, designs, plans, working drawings, specifications and other activities essential to the acquisition, improvement, modernization, expansion or replacement of land, plan, building and equipment. Expenditures directly or indirectly related to capital expenditures, such as grading, paving, taxes assessed during the construction period and costs involved in demolishing or razing structures are also included. Transactions which are separated in time but are components of one overall plan or patient care objective are viewed in their entirety without regard to their timing. Other costs related to a capital expenditure include title, permit and license fees, broker commissions, architect, legal, accounting, and appraisal fees, interest, finance or carrying charges on bonds, notes and other costs incurred for borrowing funds. Where the costs of the above total $100,000 or more, a capital expenditure plan must be developed.

Standard (e): Patient Care Policies.--These policies comprise the basic operating framework of the CORF and are critical to its effective operation. All policies must be in writing and documentation must verify the input of the group of professional personnel in policy development and review. Interview members of the professional staff to determine if they have a working knowledge of the policies. The policies should be current, compatible with the CORF's provision of services and be responsive to the needs of the patients. Copies of all patient care policies should be reviewed.

In brief, patient care policies must reflect the following:

. all services rendered by the CORF including those which are rendered by employees or by others furnished under an arrangement;

. a description of personnel tasks during medical emergencies and specific responsibilities, where assigned;

. the types of drugs and biologicals usually kept on the premises, their use, their manner of storage, who has access to these materials and a procedure for periodic review to determine the date of limited substances;

. all criteria governing patient admission, continuing care and discharge. These criteria should coincide with professional staffing and must be as specific as possible. Factors governing admission may include geographic areas, ambulatory status of patients, specific diagnoses, patient ability to carry through on a home program, etc. Criteria developed for discharge may follow along the lines of specific levels of progress (attainment of goals), need for higher level of care etc;

. the manner in which clinical record documentation is to be prepared and maintained. At a minimum, policies should state that all personnel performing services (i.e., those defined in the conditions of participation) must sign any entry they place in the patient's clinical record regardless of whether such personnel are employees of the facility or others. Clinical records must be maintained so that easy access is afforded all CORF personnel;

. a procedure for explaining a patient's treatment program to the patient and to the patient's family. In most cases this procedure would include a discussion of the diagnosis(es), the type and reasons for treatment, the treatment goal and the type of home program, where applicable, which will be developed. In general, unless the referring physician specifically notes that certain information is not to be revealed to the patient or family, the treatment program is to be discussed in detail and procedures are to be in effect for continuing discussions as they are warranted;

. a policy that requires all patients to be under the care of a physician and that a plan of treatment for each patient must be in effect;

. a procedure to assist the referring physician in locating another level of care for patients whose treatment has terminated and who are discharged; and

. a procedure to ensure that the group of professional personnel reviews and takes appropriate action on recommendations from the utilization review committee regarding patient care policies.

Standard (f): Delegation of Authority.--The responsibility for overall administration, management and operation must be retained by the facility and not delegated to others. A CORF may delegate to others those

functions which do not, in any way, infringe upon its ability to direct and control all necessary administrative, management and operational activities. Those functions which may be delegated relate to financial management, specifically those areas noted in the regulation. A CORF may not, for example, appoint an individual to serve as an administrator who is an employee of another organization. This standard does not preclude the CORF from using personnel other than employees to furnish patient care. A contract between the CORF and another entity (e.g., a management company) for the delegation of financial management services must be in force. This contract must not be for a term that exceeds 5 years.

No provision of this contract should enable the entity to act on behalf of the CORF or give the entity any responsibilities that would enable it to alter in any way, normal operational activities.

III. COMPREHENSIVE REHABILITATION PROGRAM (42 CFR 488.58)

A. General.--Ascertain that the CORF is providing a coordinated rehabilitation program. Assimilation of information from patient care policies, plans of treatment, clinical records and staff interviews will be necessary. Review a listing of CORF services to determine that the three required services (physicians' services, physical therapy and social or psychological services) are furnished and readily available.

B. Major Sources of Information

1. Patient care policies

2. Clinical records

3. Organization chart showing administrative facility framework.

C. Standards

Standard (a): Physician Services.--Written documentation must indicate that a physician(s) who meets the qualifications in the conditions of participation performs the required physician services. Participation for at least one year in a residency program which provides training in the medical management of patients needing services such as orthopedics, neurology, neurosurgery, rheumatology, etc., meets the definition of facility physician. If physicians do not have this training, but wish to meet the definition by virtue of prior or concurrent experience in a rehabilitation setting, ascertain that this experience has been at least one year in length and consisted of activity such as developing plans of treatment, participation in patient case review conferences and establishing pertinent patient care policies. While it is preferable that this experience would have been full-time, part-time experience is acceptable. However, part-time experience should have been on a continuing weekly basis. The degree of time spent must confirm that required functions were accomplished.

Documentation must verify this training or experience. It might consist of a resume, certificates of training or letters acknowledging completion of training or experience. Review available material to verify compliance with physician qualification requirements.

The facility physician may be associated with the facility on either a part-time or full-time basis. If part-time, it is important to determine that the physician is effectively performing required responsibilities. Review the activities of the group of professional personnel, utilization review process, patient records and reports of case review conferences to ascertain the extent of physician participation in patient care activities. The extent of physician participation can be determined, in part, by the type and volume of patients, scope of services and need for consultation and medical care services. Normally, greater physician participation will be required in a facility where the patients have multiple chronic disabilities, require several services, and require frequent changes in the plan of care than in a facility where the patients have acute disabilities.

A facility physician may refer patients to the facility. CORFs may have a physician(s) providing physician services at the facility on a part-time basis and this physician(s) may have an office practice distinct from the CORF. In such cases this physician(s) may establish the CORF plan of treatment when referring patients to the CORF. If a plan of treatment has not been established by the referring physician, a facility physician is responsible for establishing a plan of treatment.

Diagnostic and therapeutic services furnished to an individual patient are not CORF physician's services and may be provided by physicians who do not meet the definition of facility physician.

Emergency physician services need not be performed by a facility physician. Rather, these services may be provided by another physician(s) or by paramedics with hospital emergency room back-up, or through other arrangements that ensures prompt delivery of emergency services. These mechanisms must be in writing, readily available and familiar to all staff. Emergency services must be available during the total operating hours of the CORF.

Standard (b) Plan of treatment.--Every patient must have a plan of treatment established, either by the facility physician, the referring physician or both in collaboration. If a plan of treatment is not established for a patient referred to a CORF, the facility physician must establish one. Usually, a plan of treatment is written; however, it is acceptable in certain circumstances for a verbal order and plan to be telephoned to the CORF by the referring physician (if a facility physician is present when the patient arrives, this physician should develop the plan of treatment if one has not been developed). The time, date, referring physician's name and contents of

the verbal order must be documented and signed by the person receiving the order, and countersigned by the referring physician as soon as possible. It may not always be appropriate for facility professional staff to be involved in the development of the plan of treatment; however, in some facilities this is normal practice. It may also be normal practice for the physician to develop treatment procedures subsequent to professional personnel evaluation and recommendations. Therefore, it is acceptable for the initial plan of treatment to be written in a general nature, i.e., providing the goals and services to be performed. However, it must be rewritten later to include specific items such as precautions and the frequency, amount and duration of services. A plan of treatment in some form must be developed prior to the beginning of patient treatment. If specific information relative to frequency, goals, etc., is not routinely incorporated with the physician referral, inform the administrator and request that corrective action be taken to avoid a re-occurrence of this problem. The plan of treatment must include all of the services needed by the patient that meet the definition of CORF services. (CORF services are: physician; physical therapy; occupational therapy; speech-language pathology; respiratory; prosthetic; orthotic; social; psychological; nursing; drugs and biologicals; and supplies, appliances and equipment). For example, if a patient is in need of social services, physical therapy and speech-language pathology, all three services must be included in the CORF plan of treatment.

After treatment has begun, any change in the plan of treatment should be supported in the patient's clinical record by dated documentation signed by either the facility physician or by the referring physician. It should be noted in the patient's clinical record whether changes in the patient's condition, staff recommendations and/or results of a patient case review conference caused the change to be made. Any change in the patient's condition must be accompanied by an evaluation and, if necessary, a revision of the plan of treatment.

The 60-day review of the plan of treatment must be performed by a facility physician who certifies that the plan of treatment is being followed and that the patient is making progress in attaining the established goals. A facility physician, in most cases, will be more familiar with the CORF's services, and the patient's status, and will have easier access to the patient's record and professional staff opinions than the referring physician. However, the referring physician should always be given the opportunity to have continued input into the patient's treatment program. In this regard, CORF staff must communicate either verbally or in writing the results of the 60-day review to the referring physician. Verbal communication should be by either a facility physician or one of the professional personnel carrying out the plan of treatment. The referring physician's verbal concurrence, or revision of the plan of treatment should be documented in the patient's clinical record by the individual communicating with the referring physician. This documentation should include the date and the subject matter discussed. The referring physician's written response should be incorporated into the patient's clinical record. While it may be preferable to temporarily suspend services until receipt of the referring physician remarks, this may not always be

practical. Record reviews will be able to show whether the referring physician's remarks have been received timely. If there appears to be a trend developing which indicates these remarks are not timely, inform the administrator.

Standard (c): Coordination of Services.--Patients receive maximum benefit from a comprehensive outpatient rehabilitation program when services are provided in a coordinated manner. In most CORFs, a multi-disciplinary team of professional personnel provides several rehabilitation services to patients. The team may include full-time and part-time employees as well as non-employees functioning on either a full-time or part-time basis. It is, therefore, important that the facility take steps to assure that services are provided in an efficient, effective and coordinated manner. The facility must designate in writing one professional to oversee the coordination activities that the facility has developed. This responsibility can be performed concurrently with the assigned person's normal professional duties.

Frequency of clinical record entries may range from a brief entry in a patient's clinical record each day the patient receives treatment, to entries of longer intervals. The facility must establish some procedure detailing the frequency of clinical record documentation. Since this documentation may be used as one of the factors in determining the outcome of the 60-day plan of treatment review, entries should appear frequently enough during each 60-day period to provide an adequate picture of the care being given and the patient's status relative to established goals.

The frequency, format, and criteria for patient case review conferences may vary among facilities. These conferences generally will be convened to determine the appropriateness of continuing treatment, changing a plan of treatment, or to coordinate treatment activities. Conferences may routinely be scheduled for each patient after the patient has been undergoing treatment for a specified period of time or has had a specified number of treatments; or conferences may be scheduled only for patients who are not meeting anticipated goals, who need a different level of care, or who are receiving an intensive multi-service rehabilitation program. There must be a written policy regarding patient case review conferences, and it should be adhered to. Review past patient case review conference documentation and interview personnel regarding its utilization. There should be a formal procedure to familiarize all personnel treating the patient with the results of the CORF's coordination of service activity.

Standard (d): Provision of Services.--All patients must be referred to the CORF by a physician. The referral should contain the patient's medical history, current medical findings, diagnosis, contraindications to any treatment modality and rehabilitation goals, if determined. Current medical findings and a complete and appropriate medical history do not always accompany a physician's referral. In such cases, a qualified professional or a facility physician should obtain this information from the patient. Obtain additional necessary information through followup with the referring physician.

CORF services may be provided by employees or by others under arrangements, i.e., individuals from an organization that has a contract with the facility to provide services, and individuals that contract directly with the CORF. Professional personnel need not be expressly employed by a CORF or function under an arrangement exclusively for a CORF. Personnel may be associated with other organizations while they are associated with the CORF, but must be available during operating hours. For example, a principal(s) of a skilled nursing facility (SNF) may also own a CORF and share personnel between these two providers. This is permissible and satisfies compliance with regulations when these personnel are able to function exclusively for each provider in carrying out assigned responsibilities. This is especially important because each CORF is a separate identifiable provider and must independently meet the Conditions of Participation.

After determining the type of services the CORF provides, ascertain that it has the equipment and personnel necessary to adequately and effectively provide these services. Determine specific equipment requirements from the plans of treatment, and verify the presence of such equipment.

A facility need not own all of the equipment required for implementing the plan of treatment. It is permissible to rent or lease necessary equipment on an as needed basis, however, there must be evidence that this equipment was and is able to be readily obtained.

The number of qualified professionals and/or others needed to adequately and effectively provide services to patients accepted for is not to be determined by a simple proportion of staff to patients. It is to be based on knowledge of the types of patients treated, and the frequency, duration and complexity of treatment required.

When supportive personnel (i.e., aides) other than those that are noted in the personnel qualification section of the Conditions of Participation (see §485.70, formerly §488.70)) are used to assist qualified professionals, their duties, responsibilities and qualifications should appear in the facility's policies and be consistent with accepted standards and practices. All supportive personnel must be instructed in specific patient care techniques by appropriately qualified personnel.

This instruction depends on assigned responsibilities, education, experience and the types of patients treated. The appropriately qualified professional must be on the premises, and supervise the care given when supportive personnel are utilized. Verify this through a review of the treatment and staffing schedule. For example, when supportive personnel are used in conjunction with the furnishing of physical therapy services, a person meeting the qualification requirements of §485.70 (formerly §488.70) must be on the premises.

Changes which need to be made concerning the implementation of the plan of treatment may be initiated by qualified professional personnel. Assistant-level personnel (as defined in §485.70 (formerly §488.70)) must not initiate such changes without the approval of the appropriately qualified professional. Ideally, all professional personnel should be on the premises of the CORF when not providing offsite therapy services. When this is not the case, personnel must be available for duty on the CORF's premises as needed, and must be able to be contacted by telephone.

At least one qualified professional (or a combination of professionals) must be on the facility's premises during its hours of operation.

It may not be unusual to find that, in a CORF which furnishes a broad array of rehabilitation services, particular aspects of care are being furnished by several types of professionals. For example, registered nurses with special training in respiratory care or physical therapists may furnish respiratory therapy services. Occupational and/or physical therapists may engage in the design and development of orthotic and prosthetic devices.

The CORF is responsible for ensuring that a practitioner furnishing a particular service is qualified to do so under State law and does so within accepted professional standards and practices. Noncompliance with §485.58(d)(7) (formerly §488.58(e)(7)) raises serious questions concerning the CORF's ability to ensure patient safety and could lead to termination from Medicare. Carefully review the qualifications of a professional providing more than one CORF service. Determine the scope of the particular service and verify that the practitioner is qualified to provide the service, and that it is provided pursuant to State law and accepted professional standards and practices.

Standard (e): Scope and Site of Services.--In general, all services must be furnished on the premises of the CORF. The only exceptions are the home evaluation visit (see §2362) and, effective December 22, 1987, physical therapy, occupational therapy, and speech pathology services. The provision allowing offsite therapy services does not permit the CORF to establish extension locations and all records must be maintained on the premises of the CORF. The purpose of the home visit is to evaluate the home environment in relation to the patient's established treatment goals. The home visit

evaluation may include assessing the need for modifying the physical and/or social environment to maximize the patient's functional capability. The home, for purposes of this home evaluation visit, is the patient's legal residence. The visit may take place anytime between the implementation of the plan of treatment and the discharge of the patient. A patient who is periodically discharged and admitted for a chronic but stable problem would not normally receive more than one home evaluation visit, even though the patient may be receiving more than one service.

Notes in the patient's clinical record should indicate when the visit was made, by whom, its purpose and the results of the evaluation.

Also, the CORF must provide all the CORF services required in the plan of treatment. Since these services may be provided by personnel under arrangements, there should be minimal difficulty in obtaining personnel to provide services regardless of the infrequency of demand for the service. The unavailability of a service forces the patient to seek the service at another location. This is contrary to one of the purposes of the CORF legislation, i.e., to remedy the situation where beneficiaries needing several rehabilitation services are required to seek them at more than one location.

NOTE: When completing the CORF Survey Report Form (HCFA-360) do not mark standard 485.58(e) (tag number 1-555) "no" if the CORF provides physical therapy, occupational therapy or speech pathology services offsite. We will revise the HCFA-360 to include this offsite provision when it is reprinted.

Standard (f): Patient Assessment.--Verify that each patient is assessed by each qualified professional personnel involved in the patient's care prior to the implementation of the plan of treatment. Compare, on a sample basis, the date the plan of treatment was established to the date of the initial assessment by the appropriate professional defined in §485.70 (formerly §488.70). When the plan of treatment specifies several rehabilitation services, the professional personnel responsible for initiating the plan may be unable to complete their respective assessments on the same day. This may result in a lapse of several days between assessments. In these situations the plan of treatment may be initiated before all professionals have assessed the patient. For example, the physical therapist may complete an assessment of the patient and initiate the physical therapy service portion of the plan before the speech pathologist assesses the patient. Reasons for this time lapse may be due to scheduling conflicts, the patient's endurance, insufficient coordination or lack of communication among staff.

If an unreasonable time lapse occurs between assessments, determine the frequency, lengths, and reasons for the time lapse. Ascertain whether the time lapse is resulting in unnecessary patient visits, uncoordinated patient care or lengthy delays in implementing the complete plan of treatment.

A patient reassessment serves as a tool to present a comprehensive picture of the patient's status at a specific point in time. Because the reassessment usually consists of the same evaluative mechanisms (e.g., test procedures, measurements, professional observations and subjective information from patient) used in the initial assessment to obtain indicators of the patient's status, the patient's status at different points in time can be compared. Since a reassessment must be performed when significant changes in the patient's condition are noted, such a comparison is useful to determine whether the current plan of treatment is appropriate.

In contrast to the information obtained in a reassessment, periodic entries in the clinical record as required in §485.58(c)(3) (formerly §488.48(c)(3)) usually contain information such as a patient's reaction to treatment, general condition of patient, significant changes in patient's status and/or changes in the intensity of treatment. These entries provide in chronological order a picture of the patient's progress in relation to the care being given.

IV. CLINICAL RECORDS (42 CFR 485.60 (formerly 488.60))

A. General.--The clinical record serves as a basis for documentation of care rendered to the patient and communication between all personnel furnishing services. Determine whether the content of the clinical record presents a total, or at a minimum, an adequate picture of the care being given.

B. Major Sources of Information

- Active and closed clinical records
- Policies regarding protection and retention of clinical records

C. Standards

Standard (a): Content.--Examine a substantial number of both active and closed clinical records and ascertain that the required material is included. If any of the material required in this standard (§485.60(a) (formerly 488.60(a)) is absent from the clinical records, review additional records to determine the prevalence of such omissions. Record the number of records reviewed and

the number and types of deficiencies observed. In determining the number of records to be reviewed, be guided by the size of the CORF's patient caseload. The larger the caseload, the larger the review sample should be.

Each patient's record should contain a summary of each patient case review conference, where appropriate, and indicate the purpose and recommendation resulting from the conference. All reports generated as a result of any meetings concerning patient care issues should be dated, signed and made a part of the record.

Ascertain that periodic progress notes are entered in the clinical records at intervals commensurate with the type and frequency of treatment. These notes are to address the progress of the patient in attaining stated plan of treatment goals. Some facilities may require a brief entry in the clinical record each day the patient receives a treatment while other facilities may require routine progress reports at longer intervals. Ascertain the time interval between progress reports. Determine whether the time interval is impeding coordination and communication in patient care activities. Regardless of the frequency of progress notes, the notes should record the patient's status in relation to the stated treatment goals.

A discharge summary should include the date and reason for discharge, a brief summary of the patient's current status and, where applicable, details regarding referral of the patient to another level of care.

All information appearing in the clinical record must be dated, appropriately signed and promptly incorporated in the record.

Standard (b): Protection of Clinical Record Information.--Active and closed clinical records are to be stored where they are protected from fire and unauthorized use. Ascertain that there are written procedures governing the use of records which specify to whom the records or copies of records may be provided, the use to which the material may be put and the circumstances describing the return of such material. Determine that written patient consent is present to allow the release of all material not authorized by law.

Standard (c): Retention and Preservation.--Review the established policy for the preservation and retention of clinical records and verify that applicable State laws or regulations are met. The facility must provide for the maintenance of clinical records in cases where the CORF ceases to function.

V. PHYSICAL ENVIRONMENT (42 CFR 488.62)

A. General.--Examine the structure housing the CORF to ascertain that it is maintained consistent with State and local building, fire and safety codes. Review the CORF policies and procedures regarding preventive maintenance and infection control to determine if they are compatible with the scope of services, the type of equipment used and type of patients accepted for treatment.

A CORF may be established on the premises of another health entity irrespective of whether this entity is already certified under Medicare as a provider or supplier of services. For example, a CORF may be established on the premises of a skilled nursing facility (SNF) and the SNF's owner(s) may either have legal responsibility for both the SNF and the CORF, or merely rent space within the SNF to the CORF's owner(s). In either situation, the CORF must be certified separately and be functionally and operationally independent. The regulatory definition of a CORF precludes the CORF, and another entity from mixing functions and operations in a common space during concurrent or overlapping hours of operation. Sharing of a common space is acceptable if the CORF is able to fully function without interruption during its scheduled hours of operation. Use of the CORF space by another entity, or host entity if the CORF is on the premises of another health facility, during CORF hours of operation is unacceptable. For example, space on the premises of a facility which is recognized as a provider of outpatient physical therapy/speech pathology (OPT/OSP) services may function as a CORF, if this space is not to be used for OPT/OSP purposes during the operating hours of the CORF.

In the same manner as space may be shared, equipment may also be shared. All common equipment must be available (on the premises of the CORF) during the CORF's hours of operation and not, at that time, be utilized by the other entity for any purpose. (Please refer to standard(d) page K-13 for an explanation of sharing of staff).

The CORFs must be surveyed pursuant to the CORF conditions of participation and all standards must be surveyed independent of any findings resulting from the completed survey of the other entity. That is, although there may have been no deficiencies noted during the survey of the other entity, this fact must not influence any determination with respect to the survey pursuant to the CORF conditions of participation.

B. Major Sources of Information

1. Applicable State and local laws

2. Inspection reports of State and local building and fire authorities

3. Organization policies and procedures regarding maintenance of equipment, buildings and grounds.

C. Standards

Standard (a): Safety and Comfort of Patients.--Review available reports of State and local personnel responsible for enforcement of building, fire and safety codes and verify that the CORF is in compliance with applicable codes. All areas occupied or accessible to the facility for use during emergency or non-emergency activity, including corridors and stairways, are to be protected by easily accessible fire extinguishers. Lights, supported by an emergency power source, must be placed at exits. Where there is a CORF established on the premises of another health entity, also survey those areas which are common to both, i.e., corridors, stairways, storage areas, etc.

The fire alarm system must be adequate to alert personnel in time for safe evacuation of the building. The system should consist of either a manual (pull type) fire alarm system with or without automatic fire department response, or an automatic detection system along with an audible manual alarm. Any system should have the capacity for manual activation that triggers an audible in-house alarm which alerts personnel, patients and the public to the present danger and need for action. Where the alarm system is activated by a disruption of the electrical system or in other ways dependent on it, an emergency power source with automatic triggering, e.g., battery or auxiliary generator, must be available to serve as a backup. In the absence of State or local requirements, the above systems are to be approved by the State Fire Marshall's Office.

The number of staff necessary to evacuate patients during an emergency depends largely on the number and types of patients scheduled to be on the premises at any one time. A patient population consisting largely of patients dependent

on assistive devices for ambulating (e.g., canes, crutches and walkers), wheelchair bound patients and other patients who would need assistance from CORF personnel for a quick, safe evacuation, would require the presence of more staff than a patient population which is dependent on ambulatory assistive devices.

An emergency power source must be supplied, e.g., by battery or auxiliary generator, to assure adequate lighting during emergency operation within the treatment areas or those passageways, stairwells and exits (as noted above) accessible to the CORF. In cases of power outage, the emergency power source should respond either automatically or require only minimal activation effort.

Verify that the temperature and ventilation is maintained at a comfortable level.

Standard (b): Sanitary Environment.--The facility must maintain a sanitary environment and establish a program to identify, investigate, prevent and control the cause of patient infections. Review the written policies and procedures regarding infection control and maintenance of a sanitary environment. Verify that they are sufficient in light of the volume and types of patients and services provided, and that there is consistency with current practices of infection control. Identify the individual or group responsible for establishing, implementing and monitoring the policies and procedures. The facility must monitor the infection control program to ensure that policies and procedures are being complied with and are consistent with currently accepted practices. Pay particular attention to the policies, procedures and reports concerning the care and debridement of wounds, and the cleaning and disinfection of equipment such as whirlpools and paraffin baths and respiratory therapy equipment.

Verify the general sanitation, cleanliness and orderliness of the premises and verify that clean and soiled linen is handled in an orderly and sanitary manner that will prevent the spread of infection. There must be an adequate supply of fresh linen (sheets, towels, pillow cases) which must be stored and processed separate from soiled linen. Soiled linen must be processed and stored in an area away from patients, personnel and the public.

Standard (c): Maintenance of Equipment, Physical Location and Grounds.--All equipment should be inspected by CORF personnel at least yearly or more frequently depending on equipment condition and its frequency of use. Written procedures regarding the preventive maintenance program must include the following: equipment to be inspected, a brief statement concerning the general inspection process and frequency of inspection for each piece of equipment. For all electrically powered patient care equipment, appropriate manufacturer's operating and maintenance information must be on file. Review this information and ascertain what specific manufacturer's recommendations, if any, are made for equipment calibration checks, periodic maintenance procedures, etc. Then, through copies of service repair statements or other documentation, determine whether such recommendations were followed.

The facility must be free of hazards to the health and safety of patients, personnel and the public, e.g., broken window and door panes, obstruction of passageways and dangerous floor surfaces, and any hazardous exterior walkways or parking areas. Hazards are to be brought to the attention of CORF personnel.

Standard (d): Access for the Physically Impaired.--Inspect the premises to verify whether the facility ensures safe access and adequate space to maneuver in waiting areas, treatment areas and toilet facilities for all physically impaired patients including those on stretchers or in wheelchairs. Make sure that at least one toilet facility is able to be used by ambulatory and nonambulatory patients, that is, grab bars are provided, elevated toilets seats are available, etc. Verify that doorways, stairwells, corridors are of adequate width to allow for safe movement of all patients, that stairwells are equipped with a handrail on at least one side and that at least one entrance is usable by individuals in wheelchairs. A wheelchair entrance must be equipped with a suitable ramp if needed.

VI. DISASTER PROCEDURES (42 CFR 488.64)

A. General.--A well developed disaster plan is to be documented and posted in areas accessible for continuing personnel review.

B. Major Sources of Information

l. Disaster plan

2. Documentation as to ongoing training sessions and dates of disaster drills

C. Standards

Standard (a): Disaster Plan.--Ascertain that the disaster plan is documented and includes the assignment of responsibilities to CORF personnel, evacuation routes, and procedures for the transfer of records and casualties. In addition, verify that the plan includes procedures for notifying community emergency personnel, procedures for leaving the facility and instructions regarding the location and use of alarms and fire fighting equipment. Interview staff to ascertain their familiarity with the plan. The plan should be posted where it can be easily seen by patients and the public.

The CORF is responsible for ensuring that all personnel (employees and others) are knowledgeable of their responsibilities and have been trained in carrying them out. The CORF must train and instruct all personnel in disaster preparedness responsibilities. Larger, more complex CORFs would most likely provide ongoing training more frequently than smaller CORFs. The date of training and names of those persons taking part are to be documented. Verify from this documentation that all personnel have been instructed and

trained in their responsibilities and that all new personnel are properly trained within 2 weeks of their first workday.

VII. UTILIZATION REVIEW PLAN (42 CFR 488.66)

A. General.--Each facility must have in effect, a written utilization review plan. An established utilization review plan serves to indicate how well policies are functioning, how effective treatment regimens have been, and how well the CORF has adopted its particular program to selected patients.

B. Major Sources of Information

1. Clinical records

2. Written utilization plan

C. Standards

Standard (a): Utilization Review Committee.--The committee must meet at least quarterly. It is the responsibility of the CORF to make sure that a facility physician participates in the review process, either as a primary review member or as a post review participant. Verify that a facility physician has been involved.

Standard (b): Utilization Review Plan.--Ascertain that the plan contains specific procedures and standards necessary to perform the required evaluations. The number of cases selected for review and the frequency of reviews should be outlined in the plan. Cases reviewed should be representative of the types of patients treated at the CORF and the types of services provided.

Ascertain whether the utilization review plan is being followed. Reports and outcomes of evaluations should be reflected in the minutes of the utilization review committee. Those minutes should also indicate the extent to which the CORF program, policies and practices are being followed.

Results of utilization review activities should be made available to all professional personnel. Identify whether the results of the review prompted recommendations concerning CORF policies and practices and whether the recommendations were communicated to the administrator and governing body and the group of professional personnel (if different from utilization review committee).

APPENDIX L

AMBULATORY SURGICAL SERVICES

INTERPRETIVE GUIDELINES AND SURVEY PROCEDURES

Appendix L

Interpretive Guidelines and
Survey Procedures - Ambulatory Surgical Services

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	416.2 Definitions As used in this part; "Ambulatory surgical center" or "ASC" means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with HCFA under Medicare to participate as an ASC, and meets the conditions set forth in Subpart B and C of this part.	Interpretive Guidelines: §416.2 The ASC must use its space for ambulatory surgery exclusively. Record keeping must be exclusive to the ASC, and the staff must be responsible to the ASC. For example, a nurse could not provide coverage in the ASC and in an adjacent clinic (or hospital) at the same time. The ASC is not required to be in a building separate from other health care activities (e.g., hospital, clinic, physician's office). It must be separated physically by at least semi-permanent walls and doors. The regulatory definition of an ASC does not allow the ASC and another entity to mix functions and operations in a common space during concurrent or overlapping hours of operation. Another entity may share common space only if the space is never used during the scheduled hours of ASC operation. However, the operating and recovery rooms must be used exclusively for surgical procedures. The ASC may not perform a surgical procedure on a Medicare patient when, before surgery, an overnight hospital stay is anticipated. There may, however, arise unanticipated medical circumstances that warrant a Medicare patient's hospitalization after an ASC surgical procedure. The ASC must have procedures for the immediate transfer of these patients to a hospital (42 CFR §416.41). Such situations should be infrequent. ASC covered procedures (see 42 CFR §416.65) are those that generally do not exceed 90 minutes in length and do not require more than four hours recovery or convalescent time. Thus, ASC patients generally do not require extended care as a result of ASC procedures. An unanticipated medical circumstance may arise that would require an ASC patient to stay in an overnight healthcare setting. Such situations should be infrequent. When extended care in a non-hospital healthcare setting is anticipated as a result of a particular procedure, that procedure would not be a covered ASC procedure for Medicare beneficiaries.
	416.40 Condition for Coverage- Compliance with State licensure law. The ASC must comply with State licensure requirements.	Interpretive Guidelines: §416.40 In States where licensure is required for a facility providing ambulatory surgical services, ask to see the facility's current license. If the State license is revoked, the ASC is out of compliance with this condition. This may result in its termination from participation in Medicare. Where a State has no applicable licensure requirements, or where ambulatory surgical services may be provided without licensure, a facility will be eligible if it meets the definition in §416.2 and all other applicable Medicare requirements. Failure of the facility to meet State licensure law may be cited when the authority having jurisdiction (AHJ) has made a determination of noncompliance and has also taken a final adverse action as a result. If the surveyor identifies a situation that

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		indicates the provider may not be in compliance with State licensure law, the information may be referred to the AHJ for follow-up. If the facility is not in compliance with State licensure law, the facility could be found out of compliance with §416.40.
Q3	416.41 Condition for Coverage - Governing body and management. The ASC must have a governing body, that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation and for ensuring that these policies are administered so as to provide quality health care in a safe environment. When services are provided through a contract with an outside resource, the ASC must assure that these services are provided in a safe and effective manner.	Interpretive Guidelines: §416.41 The ASC must have a designated governing body that demonstrates its oversight of ASC activities intended to protect the health and safety of patients. o An individual may act as the governing body in the case of sole-ownership, absentee ownership, or in other special cases. o Responsibilities may be formally delegated to administrative, medical, or other personnel for carrying out various activities. However, the governing body must retain ultimate responsibility. The ASC must establish and carry out activities that will ensure that contracted services are provided in a safe manner. Survey Procedures and Probes: §416.41 Review chapter or titles of incorporation, bylaws, and partnership agreements. Annotate on the survey report form if full legal responsibilities have been established.
Q4	Standard: Hospitalization. The ASC must have an effective procedure for the immediate transfer to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC. This hospital must be a local, Medicare participating hospital or a local, nonparticipating hospital that meets the requirements for payment under §482.2 of this chapter. The ASC must have a written transfer agreement with such a hospital, or all physicians performing surgery in the ASC must have admitting privileges at such a hospital.	Interpretive Guidelines: §416.41 An "effective procedure" encompasses: o Written guidelines (e.g., policies and/or procedures); o Arrangement for ambulance services; and o Transfer of medical information. Survey Procedures and Probes: §416.41 Request documentation of a transfer agreement or evidence of admitting privileges. o Policies and procedures must be established for transferring patients requiring emergency care. o Appropriate personnel should be aware of transfer procedures.

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Q5	416.42 Condition for Coverage - Surgical Services Surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the ASC in accordance with approved policies and procedures of the ASC.	Interpretive Guidelines: §416.42 "In a safe manner" means that: o The equipment and supplies are sufficient so that the type of surgery conducted can be performed in a manner that will not endanger the health and safety of the patient; o Access to operative and recovery areas is limited; o All individuals in the surgical area are to conform to aseptic techniques; o Appropriate cleaning is completed between surgical cases; o Suitable equipment is available for rapid and routine sterilization of operating room materials; o Sterilized materials are packaged, labeled, and stored in a manner to ensure sterility and that each item is marked with the expiration date; and o Operating room attire is suitable for the kind of surgical cases performed. (Persons working in the operating suite must wear clean surgical costumes in lieu of their ordinary clothing. Surgical costumes are to be designed for maximum skin and hair coverage.) Survey Procedures and Probes: §416.42 Policies and procedures should contain at a minimum: o Resuscitative techniques; o Aseptic technique and scrub procedures; o Care of surgical specimens;

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		o Appropriate protocols for all surgical procedures, specific or general in nature, and include a list of equipment, materials, and supplies necessary to properly carry out job assignments; o Procedures addressing the cleaning of operating room after each use; o Sterilization and disinfection procedures; o Acceptable operating room attire; o Care of anesthesia equipment; and o Special provision for infected or contaminated patients.
Q6	(a) Anesthetic risk and evaluation. A physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the ASC, each patient must be evaluated by a physician for proper anesthesia recovery.	Survey Procedures and Probes: §416.42(a) The medical record should confirm: o If laboratory studies were ordered as part of patient evaluation. The report should be part of the medical record or notation of the findings recorded on the chart. For general anesthesia, the evaluation should contain, at a minimum, a brief note regarding the heart and lung findings the day of surgery; and o Depending on the type of anesthesia and length of surgery, the postoperative check should include some or all of the following: --Level of activity; --Respirations; --Blood pressure; --Level of consciousness; and --Patient color.

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Q7	(b) Standard: Administration of Anesthesia. Anesthesia must be administered by only: 1. A qualified anesthesiologist, or 2. A physician qualified to administer anesthesia, a certified registered nurse anesthetist, a supervised trainee in an approved educational program, or an anesthesiologist's assistant. In those cases in which a non-physician administers the anesthesia, the anesthetist must be under the supervision of the operating physician, and in the case of an anesthesiologist's assistant, under the supervision of an anesthesiologist.	Survey Procedures and Probes: §416.42(b) The ASC indicates those persons qualified to administer anesthesia. An approved educational program is a formal training program leading to licensure or certification in anesthesia that is recognized by the State.
Q8	(c) Standard: Discharge. All patients are discharged in the company of a responsible adult, except those exempted by the attending physician.	Interpretive Guidelines: §416.42(c) Any exceptions to this requirement must be made by the attending physician and annotated on the discharge plan.
Q9	416.43 Condition for Coverage - Evaluation of quality. The ASC, with the active participation of the medical staff, must conduct an ongoing, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of care, and use	Interpretive Guidelines: §416.43 Evaluation of quality of care is a rapidly evolving area. Major changes have occurred in the field of Quality Assurance, primarily in terminology and the methods used to monitor care. Some of the changes include: o Increased emphasis on organizational systems and processes (rather than individual case review); o Increased recognition of the need for objective data;

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	findings, when appropriate, in the revision of center policies and consideration of clinical privileges.	o Increased use of quality indicators or performance measures with which to analyze patient care processes and outcomes; and o Increased emphasis on quality monitoring for identifying opportunities to improve care (rather than focusing only on problem identification). Indicators or performance measures are tools that monitor important clinical, management, support, and governance processes and outcomes. Ongoing monitoring of important processes and outcomes allows the ASC to measure performance in key areas and identify opportunities to improve care. <u>Survey Procedures and Probes: §416.43</u> Items for discussion with facility staff may include: o Describe an important opportunity to improve the patient care process or outcomes in the ASC; o How did you become aware of this particular opportunity to improve patient care; o What was done, or what would you suggest should be done, to improve the patient care process or outcome; and o Who contributed, or who would you suggest contribute, to the improvement effort. Items for review include: o How and when is quality monitoring conducted; o What key indicators of quality or performance measures are monitored by the ASC; o How the medical staff participates in quality assurance; o How appropriateness of care is reviewed; and o How policies and clinical privileges are revised to improve patient care processes? For an initial certification there are no historical records of quality monitoring to review. However, review for evidence that the ASC has outlined a program to monitor key indicators of quality and appropriateness, and that proper reporting and accountability mechanisms are in place. For existing programs, the most important factor to evaluate is whether the ASC's quality assurance or quality improvement

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		program has been implemented. Review the facility's program documentation and other records to determine whether patient quality of care and administrative issues that impact on quality have been identified. The ASC should use the results of ongoing quality monitoring to identify processes that need improvement, develop and implement corrective actions and evaluate whether the problems have been eliminated or minimized. Annotate on the survey report form what the ASC considers important processes to patient care that should be evaluated ongoing, and that are not ongoing. Ongoing means that there is continuing or periodic collection and assessment of data concerning all areas that impact on patient care. The program continually identifies processes for improvement and potential problems and indicates the data which should be collected and assessed in order to provide the ASC with routine findings regarding quality of patient care. The monitoring should be comprehensive and take into consideration medical necessity as it relates to the procedure performed by the ASC. The quality assurance or improvement program should also monitor the quality of patient education before procedures are performed and prior to discharge after the procedure. Specifically, are patients given necessary information to prepare for the procedure and to perform self-care and manage complications after discharge? Evaluation of appropriateness of care should include analysis of: o Anesthesia recovery; o Infection rates; o Pathology reports; o Nursing services; o Completeness of medical records; o Complications that have occurred; and o Stability at discharge. There should be sufficient data in the medical records to support the diagnosis and procedures appropriate to the diagnosis. The methods use for facility self-assessment may be very flexible and there may be a wide variety of assessment techniques used. Care may be assessed prospectively, concurrently, or retrospectively. Where problems (or potential problems) are identified following the above analysis, ASCs should take appropriate action as soon as possible to avoid any risk to patients. Examples of appropriate action may include: o Changes in policies, processes and procedures; o Staffing and assignment changes;

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		o Appropriate education and training; o Adjustments in clinical privileges; and o Changes in equipment or physical plant.
Q10	§416.44 Conditions for coverage-Environment. The ASC must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.	Survey Procedures and Probes: §416.44 Tour the facility and annotate on the survey report form whether the facility is adequately designed and equipped, clean and orderly, and free of hazards.
Q11	(a) Standard: Physical environment. The ASC must provide a functional and sanitary environment for the provision of surgical services.	
Q12	1. Each operating room must be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.	Survey Procedures and Probes: §416.44(a) Each operating room should be designed and equipped for the types of surgery performed and free of hazards to patients and staff (e.g., sufficient space, adequate lighting, necessary furniture).
Q13	2. The ASC must have a separate recovery room and waiting area.	

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Q 14	3. The ASC must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting the results to appropriate authorities.	Interpretive Guidelines: §416.44(a)(3) Since there is a risk of nosocomial infection there must be an active surveillance program of specific measures for prevention, early detection, control, education, and investigation of infectious and communicable diseases in ASCs. There must be a mechanism to evaluate the program(s) and take corrective action. The ASC should institute the most current recommendations of The Centers for Disease Control (CDC) and Prevention relative to the specific infection(s) and communicable disease(s). Survey Procedures and Probes: §416.44(a)(3) Annotate on the survey report form if the written policies and procedures do not contain, at a minimum: o Methods to minimize sources and transmission of infection, including adequate surveillance techniques such as; - Assessing the risk for infections and communicable diseases; - Identifying patients at risk for infections and communicable diseases; - Educating health care workers about infectious and communicable diseases; - Screening health care workers; - Providing a safe environment consistent with the most current CDC recommendations; - Providing treatment measures consistent with the most current CDC recommendation for the identified infection and/or communicable disease; and - Providing for program evaluation and revision of program, when indicated. o Sterilizing techniques for supplies and equipment; o Procedures for isolation; o Procedures for orientation of all new employees in infection control and personal hygiene; and o Aseptic technique procedures. Staff should have knowledge of infection control techniques and of the ASC's infection control program. The ASC should maintain an ongoing log that reports incidents of infection.

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Q15	(b) Standard: Safety from fire. (1) Except as provided in paragraphs (b) (2) and (3) of this section, the ASC must meet the provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (NFPA) (which is incorporated by reference) that are applicable to ASCs. (2) In consideration of a recommendation by the State survey agency, HCFA may waive, for periods deemed appropriate, specific provisions of the LSC which, if rigidly applied, would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients. (3) Any ASC that, on May 9, 1988, complies with the requirements of the 1981 edition of the LSC, with or without waivers, will be considered to be in compliance with this standard, so long as the ASC continues to remain in compliance with that edition of the LSC.	Interpretive Guidelines: §416.44(b) The provisions of the NFPA (1985 edition) Life Safety Code, (unless facility is grandfathered under the 1981 LSC provisions prior to May 5, 1988) that apply are: o Section 12-6 and Chapter 26, whichever provisions are more stringent, for new facilities and building permits issued or plans reviewed on or after May 5, 1988, (September 7, 1982, for facilities grandfathered under the 1981 LSC provisions); or o Section 13-6 and Chapter 27, whichever provisions are more stringent, for facilities and building permits issued or plans reviewed prior to May 5, 1988, (September 7, 1982, for facilities grandfathered under the 1981 LSC provisions). Survey Procedures and Probes: §416.44(b) The State fire authority should be used to conduct an LSC survey. This is usually the LSC unit of the State Health Department or the Office of the State Fire Marshal. It is the same unit which conducts LSC surveys for hospitals and nursing homes. Whenever a waiver is requested, submit documentation of "unreasonable hardship" and "no adverse effects on health safety" along with your recommendations through the SA to the HCFA Regional Office. The HCFA Regional Office will grant or deny the waiver.

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Q16	(c) Standard: Emergency equipment. Emergency equipment available to the operating rooms must include at least the following:	
Q17	1. Emergency call system. 2. Oxygen. 3. Mechanical ventilatory assistance, equipment including airways, manual breathing bag, and ventilator. 4. Cardiac defibrillator. 5. Cardiac monitoring equipment. 6. Tracheostomy set. 7. Laryngoscope and endotracheal tubes. 8. Suction equipment. 9. Emergency medical equipment and supplies specified by the medical staff.	
Q18	(d) Standard: Emergency personnel. Personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the ASC.	Survey Procedures and Probes: §416.44(d) Request documentation of personnel trained in the use of emergency equipment and in cardiopulmonary resuscitation. Request documentation that indicates these personnel are available at all times for emergencies.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
Q19	§416.45 Condition for coverage-Medical staff. The medical staff of the ASC must be accountable to the governing body.	Interpretive Guidelines: §416.45 The organization of the medical staff is left to the discretion of the ASC governing body. (Membership on the governing body may include physician and non-physician practitioners.) Privileges granted, however, must be consistent with the license to practice in the State and the experience of each clinical practitioner.
Q20	(a) Standard: Membership and clinical privileges. Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges in accordance with recommendations from qualified medical personnel.	Interpretive Guidelines: §416.45(a) The ASC is not required to follow each recommendation (e,g., acceptance or denial of privileges), but granting of privileges must be supported by recommendations. Survey Procedures and Probes: §416.45(a) Select no more than five personnel records for medical staff members that have been granted clinical privileges and annotate on the survey report form if there is no documentation of personnel qualifications, privileges granted, appropriate records and other related documents.
Q21	(b) Standard: Reappraisals. Medical staff privileges must be periodically reappraised by the ASC. The scope of procedures performed in the ASC must be periodically reviewed and amended as appropriate.	Survey Procedures and Probes: §416.45(b) The policies and procedures manuals should state how often reappraisals are to be conducted. Select no more than five personnel records for medical staff members that have been granted clinical privileges and annotate on the survey report form if there is no documentation of reappraisals being performed timely.
Q22	(c) Standard: Other practitioners. If the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.	Interpretive Guidelines: §416.45(c) Patient care responsibilities (which may or may not include formal privileges) may be assigned to practitioners not meeting the definition of physician in §1861(r) of the Act. However, policies and procedures must be established (e.g., either as part of overall medical staff bylaws or as separate documents) to oversee their clinical activities. "Physician" is defined in §1861(r) of the Social Security Act as: o Doctor of medicine or osteopathy; o Doctor of dental surgery or of dental medicine; o Doctor of podiatric medicine;

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		o Doctor of optometry with respect to services legally authorized to be performed in the State; and o Chiropractor with respect to treatment by manual manipulation of the spine (to correct subluxation diagnosed by X-ray). All of the above must practice in accordance with State licensure.
Q23	§416.46 Condition for coverage - Nursing Service The nursing services of the ASC must be directed and staffed to assure that the nursing needs of all patients are met.	
Q24	(a) Standard: Organization and staffing. Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ASC.	Interpretive Guidelines: §416.46(a) "Available" means on the premises and sufficiently free from other duties, enabling the individual to respond rapidly to emergency situations. Functions, qualifications, and patient care responsibilities should be delineated for all nursing personnel. Survey Procedures and Probes: §416.46(a) Select a random sample of surgical cases. Annotate on the survey report form if registered nurses are not onsite and available for emergencies during ASC hours of operation. ASC policy must explain current acceptable standards of practice. "Recognized standards of practice" are standards promoted by national, State, and local nursing associations, relating to safe and effective nursing services.
Q25	416.47 Condition for coverage- Medical records. The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.	Survey procedures and Probes: §416.47 Medical records should be properly indexed and readily retrievable. Make sure that medical records are protected from fire and unauthorized access, and are properly stored. The policy manual must address retention, preservation, and confidentiality of the medical records.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
Q26	(a) Standard: Organization. The ASC must develop and maintain a system for the proper collection, storage, and use of patient records.	Survey Procedures and Probes: §416.47(a) If patient records are not collected in a systematic manner for easy access, annotate this on the survey report form. Request six patient records and observe whether the facility has a functioning medical record system that safeguards the retention of medical records.
Q27	(b) Standard: Form and content of record. The ASC must maintain a medical record for each patient. Every record must be accurate, legible, and promptly completed. Medical records must include at least the following:	Survey Procedures and Probes: §416.47(a) Select a random sample of records to evaluate the completeness of information, recording of treatment/services provided, and content as specified in this standard. The random sample should include a sample of records from all practitioners. If you identify specific problems or trends of incomplete records, select additional records.
Q28	1. Patient identification. 2. Significant medical history and results of physical examination. 3. Pre-operative diagnostic studies (entered before surgery), if performed. 4. Findings and techniques of the operation including a pathologist's report on all tissues removed during surgery, except those exempted by the governing body.	Survey Procedures and Probes: §416.47(b)(2) The medical history and physical examination should be relevant to the reason for surgery and the type of anesthesia planned. It should validate the need for surgery balanced against the risk factors associated with anesthesia (e.g., smoking history, problems associated with past anesthesia). Record any inconsistencies on the survey report form. Survey Procedures and Probes: §416.47(b)(4) Request the list of approved exemptions. Exemptions to a pathology report should be made only when the quality of care is not compromised by the exemption and when another suitable means of verification of removal is employed. In these cases, the authenticated operative report must document the removal. Exceptions to sending specimens to the pathologist for evaluation could be made for such limited categories as foreign bodies, teeth, or other specimens that by their nature or condition do not permit fruitful examination.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	5. Any allergies and abnormal drug reactions. 6. Entries related to anesthesia administration. 7. Documentation of properly executed informed patient consent. 8. Discharge diagnosis.	Request the list of exemptions that have been approved by the governing body. Annotate on the survey report form if these exemptions appear inappropriate. Select five medical records and annotate whether the exemptions contained therein are consistent with those exemptions previously approved.
Q29	416.48 Condition for coverage-Pharmaceutical services. The ASC must provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual designated responsible for pharmaceutical services.	Interpretive Guidelines: §416.48 "Accepted professional practice" and "acceptable standards of practice" mean patient care standards established by national, State, and local professional associations regarding clinical use of drugs and biologicals. There should be records of receipt and disposition of all controlled drugs. The label of drug containers should have the name, strength, directions for use and expiration date of the drug. Survey Procedures and Probes: §416.48 Record whether there are procedures for disposal of discontinued, outdated, and deteriorated drugs. Drugs and biologicals must be current, not outdated, and properly refrigerated, if necessary. Annotate on the survey report form if no one is designated the responsibilities for pharmaceutical services.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
Q30	(a) Standard: Administration of Drugs. Drugs must be administered according to established policies and acceptable standards of practice.	
Q31	(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.	Survey Procedures and Probes: §416.48(a)(1) The ASC must have policies and procedures in place covering the administration and preparation of drugs and reporting of adverse drug reactions. Request five patient records and note if the procedures are being followed.
Q32	(2) Blood and blood products must be administered only by physicians or registered nurses.	Survey Procedures and Probes: §416.48(a)(2) The ASC must have policies and procedures that identify who is authorized to administer blood and blood products.
Q33	(3) Orders given orally for drugs and biologicals must be followed by a written order and signed by the prescribing physician.	Survey Procedures and Probes: §416.48(a)(3) Record whether medication orders are signed by the physician. Select five medication cards and annotate on the survey report form if they confirm the physician's order, i.e., that drug, dosage, and administration are as directed.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
Q34	416.49 Condition for coverage- Laboratory and Radiologic Services If the ASC performs laboratory services, it must meet the requirements of Part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of part 493 of this chapter. The ASC must have procedures for obtaining radiologic services, from a Medicare approved facility to meet the needs of patients.	Interpretive Guidelines: §416.49 ASC policies and procedures should list the kinds of laboratory services that are provided directly by the facility, and services that are provided through a contractual agreement. Review the contractual agreements and determine if the referral laboratory is a CLIA-approved laboratory. Policies and procedures should encompass the following: o A well-defined arrangement (need not be contractual) with outside services; o Laboratory services that are provided by the ASC; o Routinized procedures for requesting lab tests and radiological exams; and o Incorporate lab/radiological reports into patient records. When laboratory tests are performed prior to admission, the results should be readily available to the attending physician in the ASC. If the facility provides directly for all radiological services, the surveyor is to apply either the Condition of Participation for Hospitals at §482.26 - Radiology Department, or the Conditions for Coverage of portable X-ray services at §§405.1411-405.1416. If the services are provided for other than patients of the ASC, the facility could not be certified as an ASC. (See §416.2, Definition.) When the ASC fails to meet either the radiology requirement for hospitals or portable X-ray requirement, then all radiology services must be obtained from a Medicare- approved facility. Note, however, that a Medicare-approved portable X-ray supplier is not a facility and cannot provide X-ray services to an ASC. Portable X-ray services must be furnished in a place of residence used as the patient's home (as detailed in 42 CFR 410.32(a)(2)).

APPENDIX M

HOSPICE

SURVEY PROCEDURES
AND
INTERPRETIVE GUIDELINES

APPENDIX M

Survey Procedures and Interpretive Guidelines for Hospices

Part I

I. Introduction

II. Survey Focus

III. Survey Tasks

- Task 1. Pre Survey Preparation
- Task 2. Entrance Interview
- Task 3. Information Gathering
  Clinical Record Review
  Hospice Home Visit Procedures
- Task 4. Information Analysis
- Task 5. Exit Conference
- Task 6. Formation of the Statement of Deficiencies

Part II

Guidance to Hospice Surveyors

Column I. Tag Number

Column II. Regulation

Column III. Guidance to Surveyors (Interpretive Guidelines and Survey Probes)

I. INTRODUCTION

Survey protocols and Interpretive Guidelines are established to provide guidance to personnel conducting surveys of hospices. They serve to clarify and/or explain the intent of the regulations and are required to be used by all surveyors assessing compliance with Federal requirements. The purpose of the protocols and guidelines is to direct the surveyor's attention to certain avenues for investigation in preparation for the survey, in conducting the survey, and in evaluation of the survey findings.

These protocols represent the view of the Health Care Financing Administration (HCFA) on relevant areas and items which must be inspected/reviewed under each regulation. The use of these protocols promotes consistency in the survey process. The protocols also assure that a facility's compliance with the regulations is reviewed in a thorough, efficient, and consistent manner so that at the completion of the survey the surveyors have sufficient information to make compliance decisions.

Although surveyors use the information contained in the Interpretive Guidelines in the process of making a determination about a hospice's compliance with the regulations, these guidelines are not binding. Interpretive Guidelines do not establish requirements that must be met by hospices, do not replace or supersede the law or regulations, and may not be used alone as the sole basis for a citation. All mandatory requirements for hospices are set forth in relevant provisions of the Social Security Act and in regulations.

The Guidelines do however, contain authoritative interpretations and clarification of statutory and regulatory requirements and are used to assist surveyors in making determinations about a hospice's compliance.

TYPES OF HOSPICE SURVEYS

A. Initial Certification Surveys.--At the time of the survey, the hospice must be operational, have accepted patients (who are not required to be Medicare patients), be providing all services needed by the patients actually being served, and have demonstrated the operational capability of all facets of its operations. In the event that the hospice patients presently being served do not require the full scope of hospice services, verify that the hospice is fully prepared to provide all services necessary to meet the hospice Conditions of Participation.

It is not necessary to schedule another survey to inspect the arranged-for inpatient services **if** the contracts have been reviewed and there is no doubt that the hospice is providing the service or is fully prepared to provide the service when needed. However, the effective date of Medicare participation can be no earlier than the date the hospice is prepared to provide all of the required services and meets all the hospice Conditions of Participation. In no case can the effective date be earlier than the date of the survey.

All initial and recertification hospice surveys must verify compliance with all the regulatory requirements contained in 42 CFR 418.50-418.100.

B. Recertification Survey of Participating Hospices.--Follow the procedures for initial surveys.

C. Follow-Up Surveys.--The nature of the deficiencies dictates the necessity for and scope of the follow-up visit. The purpose of the follow-up survey is to re-evaluate the specific care and services that were cited during the survey that cannot be adequately assessed by mail or telephone contact. Assess the status of the corrective actions being taken on all deficiencies cited on the HCFA-2567. In those circumstances where an onsite follow-up visit is necessary, examine as many conditions as needed to determine compliance status.

D. Complaint Investigations.--Investigation and resolution of complaints is a critical certification activity. Each complaint against a hospice must be investigated and resolved. (See §3281.)

II. THE SURVEY FOCUS

The outcome-oriented survey process for hospices places emphasis on the effects of the hospice's performance on the patients receiving hospice services and directs the focus of the surveyor, at least initially, to the services the hospice is providing to its patients. The surveyor then examines the structures and processes contributing to the quality of these services.

The principal focus of the survey is on the outcome of the hospice's practices in implementing hospice requirements and providing hospice services, i.e., the effect of the hospice's services on the patients. The intent of the survey process is to evaluate each of the conditions in the most efficient manner possible. Instead of proceeding condition by condition through the requirements, consider the interrelatedness of the regulations. Assess each condition concurrently through observation, interviews, record reviews, and home visits, if appropriate. Direct your principal attention to how skillfully and effectively the staff interacts with the patient/caregiver, how effective the plan of care is in meeting the needs of the patient/caregiver, and how responsive the patient/caregiver is to the hospice's interactions and interventions.

III. THE SURVEY TASKS

A survey of a hospice consists of the following tasks and an assessment of the principal components listed below.

- Task 1 Pre-Survey Preparation
- Task 2 Entrance Interview
- Task 3 Information Gathering
- Task 4 Information Analysis
- Task 5 Exit Conference
- Task 6 Formation of the Statement of Deficiencies

Task 1 - Pre Survey Preparation

Prior to each survey, review the hospice's file in accordance with §2704. Also, review the information in the State files relating to the disclosure of information statement made by the hospice. Check this information for accuracy with the information obtained during the course of the survey.

Task 2 - Entrance Interview

The entrance interview sets the tone for the entire survey. Upon arrival, the surveyor or team leader should present identification, introduce any team members, inform the hospice administrator, director, or supervisor of the purpose of the survey, explain the survey process, and estimate the time schedule for completion. Surveyor(s) should be organized and courteous and aware of the fact that the unannounced survey may be disruptive to the normal daily activities of the hospice. Information should be requested and not demanded from the hospice personnel. Be sure to inform the hospice that you may conduct visits to patients as part of the certification process, and request a current list of all hospice patients receiving care.

Task 3 - Information Gathering

This task includes an organized, systematic, and consistent gathering of information necessary to make decisions concerning the hospice's compliance with each of the regulatory requirements reviewed during the survey.

A. Clinical Record Review.--Select a representative sample of clinical records according to the following guidelines:

Number of Hospice Patients Admitted During Recent 12 Month Period	Minimum Number of Record Reviews of Patients Admitted During Recent 12 Month Period
less than 150	3
150 - 750	4
751 - 1250	6
1,251 or more	8

The sample selected is to capture the different types of settings in which the hospice provides care (i.e., routine home care in a private residence or nursing facility, as well as inpatient care provided directly or under arrangement), and is to include patients with different types of terminal diagnoses. In addition to the clinical records (active and closed), request the policies and procedures, personnel files, documentation of home health aide training and/or competency evaluations, and other relevant documents, as necessary.

Throughout your survey maintain an open and ongoing dialogue with hospice personnel. Discuss your observations, as appropriate, with team members and hospice personnel. Give the hospice the opportunity to provide you with additional information in considering any alternative explanations before you make compliance decisions. Pay particular attention to the following areas:

1. Assessment of the Plan of Care

o Care is furnished according to the plan of care.

o Care is directed at managing pain and other uncomfortable symptoms and is revised and updated as necessary to reflect both the patient's current status and the family/caregiver's needs.

o All covered services are available as necessary to meet the needs of the patient.

o Substantially all core services are routinely provided by hospice employees.

o Drugs and medical supplies are provided as needed for the palliation and management of the terminal illness and related conditions. Drugs are furnished in accordance with accepted professional standards of practice.

o The plan of care reflects the participation of the patient to the extent possible. The hospice communicates the plan of care to the patient/caregiver in a comprehensible way.

2. Coordination of Service/Continuity of Care

o The hospice plan of care and clinical record reflect the activities of all disciplines providing care to the patient/caregiver.

o The hospice assumes overall professional management responsibility for all contracted services.

o The hospice makes arrangements for the provision of all necessary covered hospice services.

o The hospice makes arrangements for any necessary inpatient care according to 42 CFR 418.98, and retains professional management responsibility for services furnished by inpatient facility staff.

3. Home Health Aide Services

o Home health aides who are employees of the hospice, as well as aides used by the hospice under an arrangement or contract, meet the personnel qualifications specified in 42 CFR 484.4 for "home health aide."

o Home health aide services are adequate in frequency to meet the needs of the patient.

o A hospice registered nurse provides written patient care instructions and monitors the services provided by the home health aide.

o A hospice registered nurse makes an onsite visit to the patient's residence no less frequently than every 2 weeks if aide services are provided, to assess aide services and relationships and determine whether goals are being met. The onsite visit need not be made while the aide is furnishing services.

B. Hospice Home Visit Procedures.--Home visits **must** be made to a sample of Medicare/Medicaid hospice patients during a hospice survey if one or more of the following conditions exist:

- o The hospice has been in operation less than 6 months;
- o The hospice provides routine home care to a resident(s) of a SNF,NF, or other inpatient facility;
- o The hospice had one or more conditions out of compliance during its last survey;
- o The hospice provides 3 or more services under arrangement;
- o The hospice is found to have deficiencies in the area of quality and/or delivery of services based on the onsite portion of the current survey; or
- o The surveyor determines that home visits are required to verify that the hospice is in compliance with all conditions and standards.

Even if the above conditions do not exist, home visits are to be made, if possible, since these visits yield valuable information about patient satisfaction, plan of care implementation, continuity of care, the role of volunteers, and the availability of both routine and emergency services.

1. Patient Selection For Home Visits.--When you determine that home visits are feasible or necessary, work with the hospice staff to help you identify patients who meet one or more of the following criteria:

- o Reside in a SNF/NF, or other residential facility;
- o Receive 4 or more different hospice services;
- o Receive infrequent visits from the hospice;
- o Have frequent contacts with the hospice;
- o Have been at home for 2 or more months;
- o Have made a complaint against the hospice; or
- o Receive 2 or more hospice services under arrangements made by the hospice.

Select a random sample of at least 3 or 4 of these patients to visit. In addition, the random sample selected is to capture the different types of settings in which the hospice provides routine home care (i.e., private residence, nursing facility) and include patients with different types of terminal diagnoses (i.e., cancer, AIDS.)

2. Patient's Consent.--Visit only the homes/places of residence of Medicare/Medicaid hospice patients who have given consent for the visit. Patients must understand that a home visit is voluntary and that refusal to consent to a home visit will in no way affect Medicare/Medicaid benefits. Be certain that the patient (or representative) has signed the hospice consent form before beginning the visit. You may obtain this signature upon arrival at the patient's residence if prior verbal consent has been obtained.

The hospice representative who provides the care or services should contact the patient/family/caretaker to request permission and make arrangements for the home visit. However, if you have concerns about this arrangement, you may contact the patient/family/caretaker directly and request permission to make the home visit. The contact requesting the visit should be made in a neutral, non-alarming manner, without suggesting that there is a problem.

3. Visit Procedure.--Work with the hospice administrator or his/her designee to develop a visit schedule that is the least disruptive to the usual scheduling of visits. If a patient refuses to have the surveyor accompany the hospice representative, select an alternate patient.

A home visit is more effective in assessing the scope and quality of care being provided if you are able to observe how hospice personnel implement one or more parts of the patient's plan of care. In order to observe the delivery of care, attempt to schedule most home visits at a time when the hospice is actually providing services. Use the following procedures to select patients for home/residence visits:

o Identify and select Medicare/Medicaid patients who will be visited by the hospice during the days of the scheduled hospice survey, and who meet the criteria for patient selection. The sample size should include a few more patients than the number of proposed visits to accommodate possible refusals by patients.

o Determine the dates and times of the next visits, the types of personnel making the visits (i.e., skilled nurse, home health aide, social worker), and the names of the individuals providing the services;

o If the hospice does not have any visits scheduled, invite the hospice to have one of its employees accompany you on home visits to patients that you have selected. There may be circumstances, however, that should be reviewed during a home visit without the hospice representative being present.

In certain instances (i.e. to investigate the effectiveness of the hospice's bereavement program) it may be necessary to contact the family of a deceased hospice patient. In this situation, you may conduct an interview by telephone in lieu of a home visit. Wait at least six months after the patient's death to allow the caregiver time to adjust to his/her loss.

4. Home Visit.--At the patient's home you may talk with the patient, his/her family/caregiver or both. Indicate that the primary purpose of the home visit is to evaluate the effectiveness of the hospice's services. Conduct the visit with sensitivity and understanding of the life crises that the patient and caregiver are experiencing. Do not conduct the visit as an interrogation with a display of survey forms and long lists of questions to be answered. The following probes may be helpful to use during your interview to measure patient satisfaction with the care he/she is receiving and to assess the scope and quality of the plan of care.

- Who comes to see you from the hospice?
- How frequently do you receive care and services?
- Have you ever needed to call the hospice on weekends, evenings, nights or holidays? What was your experience with this?
- Since you have been receiving care from the hospice, have you had any out-of-pocket expenses for your health care? If yes, what kinds?
- How satisfied are you with the services provided? Do you have any suggestions for improvement?

Be continuously aware that as a guest in a patient's home/residence, courtesy, common sense, and sensitivity to the importance of an individual's own environment is absolutely essential, regardless of the condition of the home.

Observe, but do not interfere with, the delivery of care or the interactions between the hospice representative and the patient/family and/or caretaker.

Discontinue the Interview If:

- The patient shows signs of being uncomfortable or seems reluctant to talk, and if after asking the patient, he or she says they would rather discontinue the discussion; or
- The patient appears tired, overly concerned, agitated, etc., and would like to end the interview; or
- In your judgment, it appears to be in the patient's best interest to end the interview.

5. Follow-up Procedures.--Check any specific patient's complaints concerning the hospice's delivery of items and services with the hospice to be sure that there are no misunderstandings and that the patient's plan of care is being followed. If hospice deficiencies are identified as a result of a home visit, cite these deficiencies on the HCFA-2567. These deficiencies could include, but are not limited to:

- Failure to follow the patient's plan of care;
- Failure to complete clinical records;
- Failure to use volunteers if required in the plan of care;
- Failure of the hospice to routinely provide substantially all core services directly to hospice patients, including those patients who are residents of nursing facilities;
- Failure to provide all covered services, as necessary, including home health aide and counseling;
- Failure to provide nursing and physician services on a 24-hour basis; or
- Failure to retain professional management responsibility for all services provided under arrangement.

Task 4 - Information Analysis

A. General.--Do not make an evaluation of whether a finding constitutes a deficiency or whether a condition level deficiency exists until all necessary information has been collected. Review all your findings and use your professional judgement to decide whether further information is necessary.

B. Analysis.--Analyze your findings relative to each requirement for the effect or potential effect on the patient(s), the degree of severity, frequency of occurrence, and the impact on the delivery of services. An isolated incident that has little or no effect on the delivery of patient services does not warrant a deficiency citation. On the other hand, a condition may be considered out of compliance for one or more deficiencies if, in your judgement, the deficiency constitutes a significant or a serious problem that adversely affects, or has the potential to adversely affect patients. A deficiency must be based on the statute or the regulations. Citation of a deficiency must not be based on a violation of a guideline alone. In each case you must determine, based on the facts and circumstances existing at the time and any further investigation as may be warranted, whether a deficiency exists based on the applicable statutory or regulatory provision.

Task 5 - Exit Conference

General Objective.--The exit conference is held at the end of the survey to inform the hospice of observations and preliminary findings of the survey. Because of ongoing dialogue between surveyors and hospice staff during the survey, there should be few instances where the hospice is not aware of the surveyor concerns prior to the exit conference. Implement the following guidelines during the conference:

- Conduct the exit conference with the hospice administrator, director, supervisor and other staff invited by the hospice;
- Provide instructions and time frame necessary for submitting a plan of correction. (See § 2724.);
- Describe the regulatory requirements that the hospice does not meet and the findings that substantiate these deficiencies; and
- Present the HCFA-2567 onsite, or in accordance with the State agency's policy, but no later than 10 calendar days after the exit conference.

Refer to § 2724 for additional information on the exit conference.

Task 6 - Formation of the Statement of Deficiencies

Follow § 2728 for preparation of the Statement of Deficiencies and Plan of Correction. Refer to the document "Principles of Documentation for the Statement of Deficiencies" for detailed instructions on completing the HCFA-2567.

Appendix M

Interpretive Guidelines - Hospice

Conditions of Participation

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§418.3 Definitions. For purposes of this part-- **Attending physician** means a physician who-- (a) Is a doctor of medicine or osteopathy; and (b) Is identified by the individual, at the time he or she elects to receive hospice care, as having the most significant role in the determination and delivery of the individual's medical care. **Bereavement counseling** means counseling services provided to the individual's family after the individual's death. **Employee** means an employee (defined by section 210(j) of the Act) of the hospice or, if the hospice is a subdivision of an agency or organization, an employee of the agency or organization who is appropriately trained and assigned to the hospice unit. "Employee" also refers to a volunteer under the jurisdiction of the hospice. **Hospice** means a public agency or private organization or subdivision of either of these that--is primarily engaged in providing care to terminally ill individuals.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	Physician means physician as defined in §410.20 of this chapter. **Representative** means an individual who has been authorized under State law to terminate medical care or to elect or revoke the election of hospice care on behalf of a terminally ill individual who is mentally or physically incapacitated. **Social worker** means a person who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education. **Terminally ill** means that the individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
L100	418.50 Condition of Participation - General Provisions.	
L101	418.50(a) Standard: Compliance. A hospice must maintain compliance with the conditions of this subpart and subparts D and E of this part.	418.50(a) Guidelines: The hospice Conditions of Participation apply to all patients of the hospice (Medicare and non-Medicare) with the exception of the following regulations (which apply only to Medicare beneficiaries): §418.60 - The continuation of care requirement; and §418.98(c) - The 80-20 inpatient care limitation.
	418.50(b) Standard: Required Services.	
L102	A hospice must be primarily engaged in providing the care and services described in §418.202, must provide bereavement counseling and must-	418.50(b) Guidelines: The hospice must be primarily engaged in providing services to hospice patients as specified below. A hospice cannot serve as a brokerage agent by contracting or administratively arranging for all hospice services. As required by §418.202, hospice services include, but are not limited to, the following: o Nursing services; o Physical therapy, occupational therapy, speech-language pathology services; o Medical social services; o Home health aide and homemaker services; o Physician services; o Counseling services (dietary, pastoral and other); o Short-term inpatient care; and o Medical appliances and supplies, including drugs and biologicals. In addition, the hospice must provide bereavement counseling to the patient's family/caregiver after the patient's death.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
L103	(1) Make nursing services, physician services, and drugs and biologicals routinely available on a 24-hour basis;	418.50(b)(1) Probes: How does the hospice arrange staffing to meet the varied and changing needs of its patients 24 hours a day? What evidence is there that the on-call system of the hospice is in place and operational?
L104	(2) Make all other covered services available on a 24-hour basis to the extent necessary to meet the needs of individuals for care that is reasonable and necessary for the palliation and management of terminal illness and related conditions; and	
L105	(3) Provide these services in a manner consistent with accepted standards of practice.	418.50(b)(3) Guidelines: Accepted standards of practice are typically developed by professional associations such as nurses, therapists, and social workers, to establish the standards of practice for competent persons serving in a particular professional role. The accepted professional standards and principles that the hospice and its staff must comply with include, but are not limited to, the hospice Federal regulations, State practice acts, and commonly accepted health standards established by national organizations, boards, and councils (i.e., American Nurses' Association, Centers for Disease Control and Prevention (CDC)) and the hospice's own policies and procedures. Any deficiency cited as a violation of accepted standards and principles must have a copy of the applicable standard provided to the hospice along with the statement of deficiencies. A hospice may also be surveyed for compliance with State practice acts for each relevant discipline. Any deficiency cited as a violation of a State practice act must reference the applicable section of the State practice act allegedly violated, and a copy of that section of the act must be provided to the hospice along with the statement of deficiencies. If a hospice has developed or adopted professional practice standards and principles for its staff, there should be information available which demonstrates that the hospice monitors its staff for compliance with these standards and principles, and takes corrective action as needed. The regulations do not impose specific standards of practice. Do not impose your own preferred standards of practice.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		418.50(b)(3) Probes: How does the hospice ensure that its employees and personnel serving the hospice under arrangement or contract provide services to patients that are within the context of accepted professional standards of practice and that, in fact, meet patient needs?
L106	418.50(c) Standard: Disclosure of information. The hospice must meet the disclosure of information requirements at §420.206 of this chapter.	418.50(c) Guidelines: This requirement refers to the disclosure of financial interest and business ownership. The State agency should have the necessary information in its files to determine compliance with this requirement. Review this information in the State files prior to the survey and compare it with the data obtained during the onsite visit.
L107	418.52 Condition of participation-Governing body.	418.52 Guidelines:
L108	A hospice must have a governing body that assumes full legal responsibility for determining, implementing and monitoring policies governing the hospice's total operation.	The designated governing body, individual, group, or corporation must have the ultimate responsibility and authority specified in writing for setting and monitoring hospice policies.
L109	The governing body must designate an individual who is responsible for the day to day management of the hospice program.	418.52 Probe: What evidence is there that the governing body's records reflect direct involvement in hospice policy development and oversight?
L110	The governing body must also ensure that all services provided are consistent with accepted standards of practice.	

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L111	418.54 Condition of participation-Medical director.	418.54 Guidelines: The medical director may be employed full-time or part-time by the hospice, although he/she need not be a paid employee. If the medical director is not a paid employee, he/she is considered a volunteer under the control of the hospice. Volunteers are defined at 42 CFR 418.3 as hospice employees to facilitate compliance with the hospice core services requirement. For Medicare certification purposes, an individual is considered a hospice employee only in the following circumstances: o The individual is a volunteer under the jurisdiction of the hospice; o The individual is an employee of the hospice, as the term employee is defined by §210(j) of the Act. In such a case, the hospice is responsible for paying the individual directly for services performed either through a salary or on an hourly or per visit basis, and the hospice is required to issue a form W-2 on his/her behalf; or o The individual is an appropriately trained employee of the agency or organization of which the hospice is a sub-division and the individual is assigned to the hospice unit. If the individual divides work time between the parent organization and the hospice, the hospice must maintain a record of the individual's assigned time to the hospice which is distinctly identifiable as hospice time. Volunteers are defined at 42 CFR 418.3 as hospice employees to facilitate compliance with the hospice core services requirement. The medical director may also be the physician representative of the interdisciplinary group (IDG) and/or an attending physician. Responsibilities of the medical director or physician member of the hospice IDG include, but are not limited to: o Certifying (in conjunction with the attending physician if applicable) that the patient is terminally ill. Terminally ill is defined by the statute to mean that the medical prognosis of life expectancy is 6 months or less if the terminal illness runs its normal course; and o Recertifying eligibility for hospice care for subsequent election periods. All certifications of terminal illness must be written, even if a single election continues in effect for two or three periods.
L112	The medical director must be a hospice employee	
L113	who is a doctor of medicine or osteopathy	
L114	who assumes overall responsibility for the medical component of the hospice's patient care program.	

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L115	418.56 Condition of participation-Professional management. Subject to the conditions of participation pertaining to services in §§418.80 and 418.90, a hospice may arrange for another individual or entity to furnish services to the hospice's patients. If services are provided under arrangement, the hospice must meet the following standards:	418.56 Guidelines: When an individual elects to receive services under the hospice benefit, the hospice assumes full responsibility for the professional management of the hospice patient's care related to the terminal illness. It is the responsibility of the hospice to ensure that all services are provided in accordance with the plan of care at all times and in all settings.
L116	418.56(a) Standard: Continuity of care. The hospice program assures the continuity of patient/family care in home, outpatient, and inpatient settings.	418.56(a) Probes: What evidence exists in the clinical record or other documentation that indicates that there is adequate ongoing communication between the hospice and a contract provider? How does the hospice ensure that the plan of care is being followed in all settings?
	418.56(b) Standard: Written agreement.	418.56(b) Probes: How does the hospice monitor and exercise control over services provided by personnel under arrangements or contracts? How and when does communication occur between the hospice and contracted facilities?
L117	The hospice has a legally binding written agreement for the provision of arranged services.	
L118	The agreement includes at least the following: (1) Identification of the services to be provided.	What evidence is there that all services provided by the contract facility are authorized by the hospice?

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L119	(2) A stipulation that services may be provided only with the express authorization of the hospice.	
L120	(3) The manner in which the contracted services are coordinated, supervised, and evaluated by the hospice.	
L121	(4) The delineation of the role(s) of the hospice and the contractor in the admission process, patient/family assessment, and the interdisciplinary group care conferences.	
L122	(5) Requirements for documenting that services are furnished in accordance with the agreement.	
L123	(6) The qualifications of the personnel providing the services.	
L124	418.56(c) Standard: Professional management responsibility. The hospice retains professional management responsibility for those services and ensures that they are furnished in a safe and effective manner by persons	418.56(c) Guidelines It is the responsibility of the IDG to provide information concerning the care of the hospice patient, to monitor this care, and to ensure that all care rendered follows the hospice plan of care.

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	meeting the qualifications of this part, and in accordance with the patient's plan of care and the other requirements of this part.	418.56(c) Probe: What evidence is there that the hospice maintains professional management responsibility for all care, including inpatient care, rendered to the patient? What evidence is there that the hospice maintains and documents communication between the contract provider and hospice staff?
L125	418.56(d) Standard: Financial responsibility. The hospice retains responsibility for payment for services.	
	418.56(e) Standard: Inpatient care.	418.56(e) Guidelines: Short-term inpatient care may be provided in a Medicare participating hospice inpatient unit, or in a Medicare participating hospital, SNF, or NF that meets the special hospice standards regarding staffing and patient areas. (See §418.100(a) and (e).) The Medicare conditions for each of these providers of service apply, as conditions always do, to all patients regardless of payment source, unless a specific exception is provided in the regulations. It is the responsibility of the hospice to establish a cooperative arrangement with the provider of inpatient care to assure that the patient's plan of care can be developed, with the consent of the patient, in a manner that is consistent with the requirements governing both the hospice and the inpatient provider. There is no limit on the number of hospitals or facilities that a hospice may have agreements with to provide inpatient care. Services provided in an inpatient setting must conform to the hospice patient's written plan of care and must be reasonable and necessary for the palliation of symptoms or management of the terminal illness. General inpatient care may be required to adjust and monitor the patient's pain control or manage acute or chronic symptoms which cannot be provided in another setting. Inpatient admission may also be furnished to provide respite for the individual's family or other persons caring for the individual at home. Respite care is the only type of inpatient care that may be furnished in a NF. However, in order to provide respite care, the NF must meet the standards specified in §§418.100(a) and (e) regarding 24 hour nursing service and patient areas. The hospice is accountable for all hospice services provided under arrangement at the above facilities.
L126	The hospice ensures that inpatient care is furnished only in a facility which meets the requirements in §418.98 and its arrangement for inpatient care is described in a legally binding written agreement that meets the requirements of paragraph (b) and that also specifies at a minimum-	
L127	(1) That the hospice furnishes to the inpatient provider a copy of the patient's plan of care and specifies the inpatient services to be furnished;	
L128	(2) That the inpatient provider has established policies	

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	consistent with those of the hospice and agrees to abide by the patient care protocols established by the hospice for its patients;	If a hospice is hospital-based, it is not necessary for the hospice to develop a formal contract with the parent hospital for the provision of inpatient care. However, a hospital-based hospice should document, either in its bylaws or in other official documents, that the hospital will be used to furnish inpatient services to hospice patients. The adequacy of the hospice care training of personnel who provide care under arrangement is measured by the demonstrated competencies of the staff in implementing the plan of care. Although Medicare regulations do not require a hospice to maintain documentation in the clinical record of the inpatient facility with which it has a contract, the hospice must ensure that the care provided in the inpatient setting is in accordance with the hospice philosophy.
L129	(3) That the medical record includes a record of all inpatient services and events and that a copy of the discharge summary and, if requested, a copy of the medical record are provided to the hospice;	
L130	(4) The party responsible for the implementation of the provisions of the agreement; and	418.56(e) Probes: How does the hospice monitor the inpatient provider for conformance with the established plan of care? How does the hospice ensure that a member of the IDG is available to the inpatient staff for consultation concerning implementation of the patient's plan of care?
L131	(5) That the hospice retains responsibility for appropriate hospice care training of the personnel who provide the care under the agreement.	
L132	418.58 Condition of participation-Plan of care.	418.58 Guidelines: Standardized plans of care are not acceptable unless each plan is individualized to meet the specific needs of the patient and caregiver. Plans of care must be established according to §418.58(a).
L133	A written plan of care must be established and maintained for each individual admitted to a hospice program, and the care provided to an individual must be in accordance with the plan.	

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L134	418.58(a) Standard: Establishment of plan. The plan must be established by the attending physician, the medical director or physician designee and interdisciplinary group prior to providing care.	418.58(a) Guideline: The physician designee must be a physician and may be the physician member of the IDG. 418.58(a) Probes: How does coordination of care occur among staff providing services to the patient?
L135	418.58 (b) Standard: Review of plan. The plan must be reviewed and updated, at intervals specified in the plan, by the attending physician, the medical director or physician designee and interdisciplinary group. These reviews must be documented.	418.58(b) Probes: How does the hospice ensure that the plan of care is revised and updated, as needed, when the patient's condition changes?
	418.58(c) Standard: Content of plan.	418.58(c) Guidelines: Hospice care focuses on palliative care rather than curative care. The goal of the plan of care is to help the patient live as comfortably as possible, with emphasis on eliminating or decreasing pain and/or other uncomfortable symptoms.
L136	The plan must include an assessment of the individual's needs and identification of services including the management of discomfort and symptom relief.	418.58 (c) Probes: What criteria does the hospice use to assess the needs of the patient and caregiver? Who is involved in this process?
L137	It must state in detail the scope and frequency of services needed to meet the patient's and family's needs.	How does the IDG decide what services the patient will receive? How does the hospice evaluate if the services provided are continuing to meet the patients' and caregivers' needs? Is there any indication that the patient needs hospice services that he/she is not receiving?

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L138	418.60 Condition of participation-Continuation of care. A hospice may not discontinue or diminish care provided to a Medicare beneficiary because of the beneficiary's inability to pay for that care.	How does the hospice monitor the delivery of services, including those provided under arrangement or contract, to ensure compliance with the hospice philosophy? 418.60 Guidelines: This condition applies to Medicare beneficiaries only.
L139	418.62 Condition of Participation-Informed Consent. A hospice must demonstrate respect for an individual's rights by ensuring that an informed consent form that specifies the type of care and services that may be provided as hospice care during the course of the illness has been obtained for every individual, either from the individual or representative as defined in §418.3.	418.62 Guidelines: Informed consent implies that the consenting individual is competent to evaluate the decision requiring consent (i.e., is able to evaluate the implications of choosing to receive hospice care.) The patient, or representative, must sign or mark the consent form. The representative must be permitted by State law to elect or revoke hospice care or terminate medical care on behalf of a terminally ill individual. With respect to an individual granted the power of attorney for the patient, State law determines the extent to which the individual may act on the patient's behalf. Hospice admission criteria should clearly define primary caregiver requirements or decision-making policies related to patients without caregivers. If the hospice requires a primary caregiver for each patient, the policy must be specified in writing in the admission criteria and discussed with the patient and family/caregiver during the initial assessment.
		418.62 Probes: How does the hospice communicate to the family/caregiver the role that it expects them to play in providing care to the patient? What evidence of informed consent related to care and services is documented in the patient's chart? What documentation indicates that the hospice advised the patient of all the services available to the patient?

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L140	418.64 Condition of participation-Inservice training. A hospice must provide an ongoing program for the training of its employees.	418.64 Guidelines: The adequacy of the in-service training program is measured in the demonstrated competencies of the hospice staff in consistently applying the interventions necessary to meet the needs of the patient/caregiver. The training may be done directly by the hospice or by other relevant outside organizations. 418.64 Probes: What evidence demonstrates that the hospice has developed a system to disseminate its policies, procedures, and training materials to all its staff? What evidence is there that all employees have been properly oriented to the tasks they are expected to perform, that they are kept informed of the latest changes in techniques, philosophies, pharmaceuticals, etc., and that they demonstrate these skills, when needed, in practice? How does the hospice ensure that staff can demonstrate the skills and techniques needed to do their jobs? 418.66 Guidelines: This self-assessment should include all services that were provided, and the patients' and caregivers' response to those services. It should also include those services that might have been provided but were omitted. Special attention should be given to the ability of the hospice to deal with symptom management, pain control, stress management, continuity of care, and inpatient care. Suggestions for improving care and any problems identified in providing hospice care should receive the appropriate consideration from the hospice management or governing body. 418.66 Probes: What type of system does the hospice use to monitor and evaluate the care and services it provides to its patients and their caregivers/families? How does the hospice receive, record, investigate and resolve patient grievances or complaints? Who has the overall responsibility for the development and implementation of the quality assurance program?
L141	418.66 Condition of Participation-Quality Assurance.	
L142	A hospice must conduct an ongoing, comprehensive, integrated, self-assessment of the quality and appropriateness of care provided, including inpatient care, home care and care provided under arrangements. The findings are used by the hospice to correct identified problems and to revise hospice policies if necessary.	

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L143	Those responsible for the quality assurance program must- (a) Implement and report on activities and mechanisms for monitoring the quality of patient care;	How do the medical director and IDG implement procedures to monitor quality which include at least the following: o Problem identification, assessment, correction, monitoring and documentation; o Policy implementation evaluations and monitoring of staff performance; o Recommendations to the administrator and governing body for improving patient care; and o Implementation of recommendations resulting from evaluations and studies?
L144	(b) Identify and resolve problems; and	
L145	(c) Make suggestions for improving patient care.	
L146	418.68 Condition of participation-Interdisciplinary group.	418.68 Guidelines: Members of the IDG must be hospice employees or employees of the agency or organization of which the hospice is a sub-division (e.g., a hospital) who are appropriately trained and assigned to the hospice unit. All IDG members have the same responsibilities regardless of whether they are employed directly, assigned, or volunteer employees of the hospice. An employee is one who meets the common law definition of employee as found in title II of the Social Security Act, or one who is a volunteer under the control of the hospice. (See §418.3, Definitions.) The hospice may involve other members of the care team in the IDG's activities. A hospice with more than one IDG group must designate a specific group to establish policies governing care and services. The IDG should conduct an ongoing assessment of each patient's and caregiver's or family's needs. "Supervision" of care may be accomplished by conferences, evaluations, discussions and general oversight, as well as by direct over-the-shoulder observations. 418.68 Probe: How does the hospice ensure that all individuals on the IDG have been trained and are competent to perform in the area(s) assigned?
L147	The hospice must designate an interdisciplinary group or groups composed of individuals who provide or supervise the care and services offered by the hospice.	

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	418.68(a) Standard: Composition of group.	418.68(a) Guidelines: The number of individuals on the IDG is not as important as their qualifications and abilities. For example, if a group member is licensed as a registered nurse and also meets the Medicare criteria to be considered a social worker under the hospice benefit, he/she would be qualified to serve on the IDG as both a nurse and a social worker. 418.68(a) Probes: Who are the members of the IDG? How are their responsibilities to provide or supervise patient care and services implemented? How do the members of the IDG document the supervision of staff providing services under the plan of care?
L148	The hospice must have an interdisciplinary group or groups that include at least the following individuals who are employees of the hospice:	
L149	(1) A doctor of medicine or osteopathy.	
L150	(2) A registered nurse.	
L151	(3) A social worker.	
L152	(4) A pastoral or other counselor.	
	418.68(b) Standard: Role of group.	418.68(b) Guidelines: As required by §418.58(a), the IDG participates in establishing the plan of care for each patient prior to providing care. This plan is reviewed regularly and revised as needed. The plan should note each contributor as well as those persons assigned to provide the care. 418.68(b) Probes: What is the IDG's policy related to: o Developing and revising patient care objectives; o Facilitating exchange of information among staff and patient/caregiver; and o Developing a mechanism whereby a continual flow of information regarding patients' and their caregivers'/families' needs is made available to the IDG staff?
L153	The interdisciplinary group is responsible for- (1) Participation in the establishment of the plan of care;	
L154	(2) Provision or supervision of hospice care and services;	

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L155	(3) Periodic review and updating of the plan of care for each individual receiving hospice care; and	
L156	(4) Establishment of policies governing the day-to-day provision of hospice care and services.	
L157	418.68(c) If a hospice has more than one interdisciplinary group, it must designate in advance the group it chooses to execute the functions described in paragraph (b)(4) of this section.	
L158	418.68(d) Standard: Coordinator. The hospice must designate a registered nurse to coordinate the implementation of the plan of care for each patient.	418.68(d) Guidelines: What evidence exists in the clinical record that a designated registered nurse coordinates the implementation of the patient's plan of care?
L159	418.70 Condition of participation-Volunteers.	418.70 Guidelines:
L160	The hospice in accordance with the numerical standards specified in paragraph (e) of this section, uses volunteers, in defined roles, under the supervision of a designed hospice employee.	Volunteers are defined at §418.3 as hospice employees to facilitate compliance with the core services requirement.

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L161	418.70(a) Standard: Training. The hospice must provide appropriate orientation and training that is consistent with acceptable standards of hospice practice.	418.70 (a) Guidelines: All required volunteer training should be consistent with the specific tasks that volunteers perform. 418.70(a) Probes: What evidence is there that the volunteers are aware of: o Their duties and responsibilities; o The persons to whom they report; o The person(s) to contact if they need assistance and instructions regarding the performance of their of their duties and responsibilities; o Hospice goals, services and philosophy; o Confidentiality and protection of the patient's and family's rights; o Family dynamics, coping mechanisms and psychological issues surrounding terminal illness, death and bereavement; o Procedures to be followed in an emergency, or following the death of the patient; and o Guidance related specifically to individual responsibilities? How does the hospice supervise the volunteers? Is there evidence that all the volunteers have received training or orientation before being assigned to a patient/family?
L162	418.70 (b) Standard: Role. Volunteers must be used in administrative or direct patient care roles.	418.70(b) Guidelines: Volunteers who are qualified to provide professional services should meet all standards associated with their specialty area. If licensure or registration is required by the State, the volunteer must be licensed or registered. The hospice may use volunteers to provide assistance in the hospice's ancillary and office activities as well as in direct patient care services, and/or help patients and families with household chores, shopping, transportation, and companionship. 418.70(b) Probe: What evidence exists that the IDG conducts an assessment of the patient/caregiver's need for a volunteer? What evidence is there documenting the roles assigned to that hospices' volunteers?

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L163	418.70(c) Standard: Recruiting and retaining. The hospice must document active and ongoing efforts to recruit and retain volunteers.	418.70 (c) Guidelines: This documentation could include evidence such as advertisements in local newspapers, bulletins, flyers, or medica announcements.
	418.70(d) Standard: Cost saving.	418.70(d) Guidelines:
L164	The hospice must document the cost savings achieved through the use of volunteers.	It is anticipated that the hospice will use volunteers to supplement the care being provided by the paid staff who work directly with patients and their family members, both in the patients' home and the inpatient setting.
L165	Documentation must include-(1) The identification of necessary positions which are occupied by volunteers;	
L166	(2) The work time spent by volunteers occupying those positions; and	
L167	(3) Estimates of the dollar costs which the hospice would have incurred if paid employees occupied the positions identified in paragraph (d)(1) for the amount of time specified in paragraph (d)(2).	

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	418.70(e) Standard: Level of activity..	418.70 (e) Guidelines: Administrative support in this context means support of the patient care activities of the hospice (i.e., clerical duties in the office) rather than general support activities (i.e., fund raising). A hospice may fluctuate the volume of care provided by volunteers after the hospice meets the required 5% minimum. 418.70(f) Probes: What relationship does the hospice have with the clergy in the community? How does the hospice ensure that all patients are at least offered the services of clergy?
L168	A hospice must document and maintain a volunteer staff sufficient to provide administrative or direct patient care in an amount that, at a minimum, equals 5 percent of the total patient care hours of all paid hospice employees and contract staff.	
L169	The hospice must document a continuing level of volunteer activity.	
L170	Expansion of care and services achieved through the use of volunteers including the types of services and the time worked, must be recorded.	
L171	418.70(f) Standard: Availability of clergy. The hospice must make reasonable efforts to arrange for visits of clergy and other members of religious organizations in the community to patients who request such visits and must advise patients of this opportunity.	

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L172	418.72 Condition of participation-Licensure. The hospice and all hospice employees must be licensed in accordance with applicable Federal, State and local laws and regulations.	418.72 Guidelines: All professional and State licenses must be available upon request. Notify the regional office (RO) if you observe non-compliance with the laws of other Federal agencies relating to the hospice program. The RO will notify the Federal agency of the observations. 418.72 Probe: How does the hospice assure that all professional employees and personnel have current licenses and/or registration? 418.72(a) Guidelines: Be aware of all State and local laws covering the licensure of hospices. In order for §418.72 to be determined NOT MET, the State or local agency must have completed action to revoke the hospice's license or the hospice must have failed to apply for a license. If a State or local agency has a licensure law, but does not revoke the hospice's license when the requirements are not met, the hospice will be considered to be in conformance with State and local laws until such time as the State license is revoked. 418.72(b) Guidelines: The hospice must have a procedure for verifying the validity of a hospice employee's license or registration. Professional and paraprofessional volunteers must meet all necessary standards, registration and licensure requirements associated with their specialty area(s) the same as if they were salaried employees. 418.74 Guidelines: The clinical record must contain sufficient information to show that the hospice is aware of the current status of the patient/caregiver, accurate documentation of the care/services provided to the patient/caregiver and the results of the care provided. A hospice which has created the option for an individual's record to be maintained electronically, rather than in hard copy, may use electronic signatures as long as there is a process for reconstruction of the information, and there are safeguards to prevent unauthorized access to the records. The following guidelines must be in place and operational before such a system would be acceptable:
L173	418.72(a) Standard: Licensure of program. If State or local law provides for licensing of hospices, the hospice must be licensed.	
L174	418.72(b) Standard: Licensure of employees. Employees who provide services must be licensed, certified or registered in accordance with applicable Federal or State laws.	
L175	418.74 Condition of participation-Central clinical records.	
L176	In accordance with accepted principles of practice, the hospice must establish and maintain a clinical record for every individual receiving care and services. The record must be complete, promptly and accurately documented, readily accessible and systematically organized to facilitate retrieval.	

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	418.74(a) Standard: Content.	o The hospice has a written policy describing the authentication policy(ies) in force at the facility; o The computer has built-in safeguards to minimize the possibility of fraud; o Each person responsible for an entry has an individualized identifier; o The hospice has the responsibility to demonstrate that the identifier is used under safeguards to assure that no one but the person assigned the code uses the code. o A secret password known only to the user is to be employed to maintain confidentiality. o The date and time is recorded from the computer's internal clock at the time of entry; o An entry is not to be changed after it has been recorded; o The computer program controls what sections/areas any individual can access or enter data, based on the individual's personal identifier (and, therefore, his/her level of professional qualifications). A hospice is not precluded by the statute or regulations from providing services at locations other than the site to which a provider number has been assigned. However, all hospice patients' clinical records must be available to the surveyor at the time of the survey. If you have concerns about the provision of services at any outlying hospice location, home visits should be made to beneficiaries receiving services from those locations. 418.74 Probe: How does the hospice ensure that the records of all patients, including those who live in outlying areas, are accurately documented, readily accessible, and systematically organized? 418.74(a) Guidelines: The use of initials is acceptable provided the record identifies the initials with the signer's signature and title. Entries are made for care, services, observations, and assessments, and are signed by the person who provided the care, service, observations, and assessment. Signed physician orders which have been sent to the hospice by facsimile (FAX) machines are acceptable. However, the hospice is responsible for obtaining original signatures if an issue surfaces that would require verification of an original signature. A hospice may store clinical and health insurance records on microfilm or optical disk imaging systems. All material must be available for review by HCFA, the intermediary, DHHS audit, or other specially designated components for bill review, audit, or other examination during the retention period. All clinical records, along with any necessary equipment to read them, must be made available during the survey.
L177	Each clinical record is a comprehensive compilation of information.	
L178	Entries are made for all services provided.	

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L179	Entries are made and signed by the person providing the services. The record includes all services whether furnished directly or under arrangements made by the hospice.	418.74(a) Probes: How does coordination of services among the various staff members occur? What documentation is there that indicates that the physician's orders in the plan of care are being implemented both in the home and the inpatient setting?
L180	Each individual's record contains (1) The initial and subsequent assessments;	
L181	(2) The plan of care;	
L182	(3) Identification data;	
L183	(4) Consent and authorization and election forms;	
L184	(5) Pertinent medical history; and	
L185	(6) Complete documentation of all services and events (including evaluations, treatments, progress notes, etc.).	
L186	418.74(b) Standard: Protection of information. The hospice must safeguard the clinical record against loss, destruction and unauthorized use.	418.74(b) Probes: How are the clinical records stored to protect them from physical destruction and unauthorized use? What written policies and procedures govern the use, removal and release of clinical records?

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L187	418.80 Condition of participation-Furnishing of Core Services.	What measures does the hospice use to protect the patient's confidentiality? 418.80 Guidelines: For certification purposes, an individual is considered an employee of the hospice if the hospice pays the individual directly for services performed on an hourly or per visit basis and the hospice is required to issue a form W-2 on his/her behalf. If a contracting service or agency pays the individual, and is required to issue a form W-2 on the individual's behalf, or if the individual is self-employed, the individual is not considered a hospice employee. A hospice employee may also be an appropriately trained employee of the agency of which the hospice is a sub-division if the individual divides work time between the parent organization and the hospice. However, the hospice must maintain a record of the individual's assigned time which is distinctly identifiable as hospice time. An individual is also considered a hospice employee if the individual is a volunteer under the jurisdiction of the hospice. See §418.3. The hospice must maintain coordination of all staff to ensure continuity of care. 418.80 Probes: What evidence is there that the core staff employed by the hospice is able to provide all needed services to hospice patients, including continuous home care, on an ongoing, routine basis? How does the hospice ensure that the services provided are consistent with the established plan of care? What evidence is there that the hospice provides training in hospice philosophy and care to contract providers? 418.82 Guidelines: This individual may also be a member of the IDG and may be a coordinator. Supervision should include clinical record review, written and/or verbal instructions, plan of care review, and observations in the clinical area. For guidelines on services provided in accordance with recognized standards of practice, see §418.50(b)(3).
L188	Except as permitted in §418.83, a hospice must ensure that substantially all the core services described in this subpart are routinely provided directly by hospice employees.	
L189	A hospice may use contracted staff if necessary to supplement hospice employees in order to meet the needs of patients during periods of peak patient loads or under extraordinary circumstances. If contracting is used, the hospice must maintain professional, financial, and administrative responsibility for the services and must assure that the qualifications of staff and services provided meet the requirements specified in this subpart. (§§418.80-418.88)	
L190	418.82 Condition of participation-Nursing services.	
L191	The hospice must provide nursing care and services by or under the supervision of a registered nurse.	

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L192	(a) Nursing services must be directed and staffed to assure that the nursing needs of patients are met.	418.82 Probe: What evidence is there that nursing services are provided based on a nursing assessment and in accordance with the plan of care?
L193	(b) Patient care responsibilities of nursing personnel must be specified.	
L194	(c) Services must be provided in accordance with recognized standards of practice.	
	418.83 Nursing services-Waiver of requirement that substantially all nursing services be routinely provided directly by a hospice. (a) HCFA may approve a waiver of the requirement in §418.80 for nursing services provided by a hospice which is located in a non-urbanized area. The location of a hospice that operates in several areas is considered to be the location of its central office. The hospice must provide evidence that it was operational on or before January 1, 1983, and that it made a good faith effort to hire a sufficient number of nurses to provide services directly. HCFA bases its decision as to whether to approve a waiver application on the following: (1) The current Bureau of the Census designations for determining non-urbanized areas.	418.83 Guidelines If a hospice claims to have a waiver, there must be written evidence from HCFA to that effect. If there is any question concerning a waiver, contact the RO.

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	(2) Evidence that a hospice was operational on or before January 1, 1983 including: (i) Proof that the organization was established to provide hospice services on or before January 1, 1983; (ii) Evidence that the hospice-type services were furnished to patients on or before January 1, 1983; and (iii) Evidence that the hospice care was a discrete activity rather than an aspect of another type of provider's patient care program on or before January 1, 1983. (3) Evidence that a hospice made a good faith effort to hire nurses, including: (i) Copies of advertisements in local newspapers that demonstrate recruitment efforts; (ii) Job descriptions for nurse employees; (iii) Evidence that salary and benefits are competitive for the area; and (iv) Evidence of any other recruiting activities (e.g., recruiting efforts at health fairs and contacts with nurses at other providers in the area); (b) Any waiver request is deemed to be granted unless it is denied within 60 days after it is received. (c) Waivers will remain effective for one year at a time. (d) HCFA may approve a maximum of two one-year extensions for each initial waiver. If a hospice wishes to receive a one-year extension, the hospice must submit a certification to HCFA, prior to the expiration of the waiver	

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	period, that the employment market for nurses has not changed significantly since the time the initial waiver was granted.	418.84 Guidelines: A social worker is defined at §418.3 as a person who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education. The social worker's services are provided in accordance with the plan of care. Because social work services must be provided under the direction of a physician, physician approval of the plan of care will satisfy the intent of this requirement. 418.84 Probe: What evidence is there that each patient/family has received an assessment of their psychosocial needs and that the plan of care has identified ways to meet the needs identified in this assessment as required by §418.58(c)? 418.86 Guidelines: The attending physician is the physician identified by the patient, at the time he/she elects to receive hospice care, as the one who is primarily responsible for the individual's medical care. (See §418.3.) Oversight of physician services in the hospice is generally considered to be the responsibility of the medical director. The medical director should complement the attending physician's care, act as a medical resource to IDG members, and assure overall continuity of the hospice program's medical services. These services, to meet general medical needs, must be provided by the hospice to the extent that they are not met by others. The most important aspect of physician services is that the individual receives appropriate measures to control uncomfortable symptoms. 418.86 Probes: How does the hospice assure that each physician maintains a current license in the State in which the physician is practicing? What evidence is there in the clinical record of physician involvement with the patient and the IDG?
L195	418.84 Condition of participation-Medical social services. Medical social services must be provided by a qualified social worker, under the direction of a physician.	
L196	418.86 Condition of participation-Physician services. In addition to palliation and management of terminal illness and related conditions, physician employees of the hospice, including the physician member(s) of the interdisciplinary group, must also meet the general medical needs of the patients to the extent that these needs are not met by the attending physician.	

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		What system is in place to ensure than any necessary medical orders are signed by a physician? Signed physician's orders that are faxed are acceptable. See guidelines at §418.74(a).
L197	418.88 Condition of participation-Counseling services.	418.88 Guidelines: Counseling services are core services and must routinely be provided directly by hospice employees. (See §418.80.) A hospice may use contracted staff for core services only under extraordinary circumstances, similar to when nursing services are provided to supplement hospice employees in order to meet patients' needs during periods of peak patient loads. If contracting is used, the hospice must continue to maintain professional, financial, and administrative responsibility for the services. If the hospice provides all of its overall counseling services directly through hospice employees, it could, in a specific situation, provide a particular counseling service entirely through a contract with an individual who is not a hospice employee or a separate entity such as a hospital. In this situation, the hospice must document in detail the extraordinary circumstances which warrant the use of contracted staff to provide core services.
L198	Counseling services must be available to both the individual and the family. Counseling includes bereavement counseling, provided after the patient's death, as well as dietary, spiritual and any other counseling services for the individual and family provided while the individual is enrolled in the hospice.	
L199	418.88(a) Standard: Bereavement counseling. There must be an organized program for the provision of bereavement services under the supervision of a qualified professional.	418.88(a) Guidelines: Bereavement counseling is provided based on an assessment of the family/caregiver's needs, the presence of any risk factors associated with the patient's death, and the ability of the family/caregiver to cope with grief. (See §418.3.) The supervisor of bereavement services may be the IDG social worker or other professional with documented evidence of training and experience in dealing with grief. Documentation for bereavement counseling does not necessarily have to be contained in the clinical record, but must be maintained by the hospice in some form in an organized, easily retrievable manner. 418.88(a) Probes: How does the hospice ensure that each patient/caregiver is assessed for the need for bereavement counseling? How does the hospice counsel those individuals who are at risk for pathological grief?
L200	The plan of care for these services should reflect family needs, as well as a clear delineation of services to be provided and the frequency of service delivery (up to one year following the death of the patient). A special coverage provision for bereavement counseling is specified §418.204(c).	

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L201	418.88(b) Standard: Dietary counseling. Dietary counseling, when required, must be provided by a qualified individual.	418.88(b) Guidelines: Dietary counseling must be available to the caregiver/family and patient, but must relate to the patient's needs rather than the personal needs of the caregiver/family. Dietary counseling may be provided to family members to enable them to prepare food for the patient. Dietary counseling should be planned by a person who has relevant education or training. The actual counseling may be delegated to another individual. The dietician does not have to be a full time employee of the hospice.
L202	418.88(c) Standard: Spiritual Counseling. Spiritual counseling must include notice to patients as to the availability of clergy as provided in §418.70(f).	418.88(c) Guidelines: At a minimum, the hospice should discuss the patient's religious preference, if any, and assist the patient in evaluating his/her spiritual needs. 418.88(c) Probe: How does the hospice address the spiritual needs/concerns of the patients? What evidence is there in the clinical record that indicates that assistance has been offered to provide the patient an opportunity for counseling with his/her choice of available clergy?
L203	418.88(d) Standard: Additional counseling. Counseling may be provided by other members of the interdisciplinary group as well as by other qualified professionals as determined by the hospice.	418.88(d) Probe: What evidence is there that the counseling services are provided by persons whose skills and training are appropriate for the counseling provided?
L204	418.90 Condition of participation-Furnishing of other services. A hospice must ensure that the services described in this subpart are provided directly by hospice employees or under arrangements made by the hospice as specified in §418.56.	418.90 Probe: How does the hospice decide what services at §§418.92-418.98 it will provide under contract and what services it will provide directly? Is there evidence that the hospice is able to provide patients with all the services described in §§418.92 - 418.98?

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L205	418.92 Condition of participation-Physical therapy, occupational therapy, and speech-language pathology.	418.92 Probe: What evidence is there that these services are provided when needed, as determined in the plan of care? How does the hospice verify that the professionals providing these services are appropriately trained and supervised?
L206	(a) Physical therapy services, occupational therapy services, and speech-language pathology services must be available, and when provided, offered in a manner consistent with accepted standards of practice.	
L207	(b)(1) If the hospice engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the FDA, such testing must be in compliance with all applicable requirements of part 493 of this chapter. (2) If the hospice chooses to refer specimens for laboratory testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.	418.92(b)(1) Guideline: Determine if the hospice is providing laboratory testing as set forth at 42 CFR 493. If the hospice is performing testing, request to see the CLIA certificate for the level of testing being performed, i.e., a certificate of waiver, certificate for physician-performed microscopy procedures, certificate of accreditation, certificate of registration or certificate for moderate or high complexity testing. Hospices holding a certificate of waiver are limited to performing only those tests determined to be in the waived category. These are: o Dipstick/tablet reagent urinalysis non-automated (includes 10 analytes); o Fecal occult blood; o Ovulation test kits - Visual color comparison tests for human luteinizing hormone; o Urine pregnancy test - visual color comparison tests; o Erythrocyte sedimentation rate (non-automated); o Hemoglobin - copper sulfate (non-automated); o Blood glucose by glucose monitoring devices cleared by the Food and Drug Administration (FDA) specifically for home use; o Spun microhematocrit; and o Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout (e.g., HemaCue). Hospices holding a certificate for physician-performed microscopy procedures are limited to performing only those tests determined to be in the physician-performed microscopy procedure category listed below or in combination with waived tests:

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		o Wet mounts, including preparations of vaginal, cervical or skin specimens; o All potassium hydroxide preparations; o Pinworm examinations; o Fern tests; o Post-coital direct, qualitative examinations of vaginal or cervical mucous; o Urine sediment examinations. These tests must be performed by a physician on his or her own patients or the patients of the medical group practice of which the physician is a member. If performed by anyone else, the performance of these tests would require a registration certificate, certificate of accreditation or certificate. If the hospice performs any other testing procedures, it would require a laboratory registration certificate. For example, if you determine that the hospice staff is only assisting a patient to use his/her own glucometer, CLIA regulations do not apply. However, if hospice staff are actually responsible for measuring the blood glucose level of patients with an FDA approved glucometer, and no other tests are being performed, request to see the facility's certificate of waiver, since glucose testing with a glucometer (approved by the FDA specifically for home use) is a waived test under the provisions at 42 CFR 493.15. If the facility does not possess the appropriate CLIA certificate, inform the facility that it is in violation of CLIA and that it must apply immediately to the HCFA for the appropriate certificate. Also, refer this facility's non-compliance to the SA personnel responsible for CLIA laboratory surveys.
L208	418.94 Condition of participation-Home health aide and homemaker services.	418.94 Guidelines: In accordance with §484.4, a home health aide must successfully complete a training and competency evaluation program or a competency evaluation program.
L209	Home health aide and homemaker services must be available and adequate in frequency to meet the needs of the patients. A home health aide is a person who meets the training, attitude and skill requirements specified in §484.36 of this chapter.	In accordance with §484.36, the aide training program must address each of the following subject areas through classroom and supervised practical training totalling at least 75 hours, with at least 16 hours devoted to supervised practical training. The individual being trained must complete at least 16 hours of classroom training before beginning the supervised practical training. "Supervised practical training" means training in a laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse or licensed practical nurse. A "pseudo-patient," not a mannequin may be used for training.

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		The aide training program and competency evaluation program must address each of the following subject areas. Subject areas preceded by an asterisk (*) must be evaluated after observation of the aide's performance of the tasks with a patient. o Communication skills. o Observation, reporting and documentation of patient status, and the care or service furnished; o Basic infection control procedures; o Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor; o Maintenance of a clean, safe, and healthy environment; o Recognizing emergencies and knowledge of emergency procedures; o Physical, emotional, and developmental needs of and ways to work with the populations served by the hospice, including the need for respect for the patient, his or her privacy and his or her property; o Adequate nutrition and fluid intake; o* Reading and recording temperature, pulse, and respiration; o* Appropriate and safe techniques in personal hygiene and grooming (including bed bath, sponge, tub, or shower bath, shampoo, sink, tub, or bed, nail and skin care, oral hygiene, toileting and elimination); o* Safe transfer techniques and ambulation; o* Normal range of motion and positioning; and o Any other task that the hospice may choose to have the home health aide perform. The hospice is responsible for ensuring that home health aides used by the hospice meet the personnel qualifications specified in §484.4 for "home health aide" and maintaining adequate documentation of compliance with the regulation. This includes home health aides trained and evaluated by other organizations, and those hired by the hospice directly, as well as under an arrangement. It is the responsibility of the hospice to ensure that its aides are proficient to carry out their patient care assignments in a safe, effective, and efficient manner. In accordance with §484.36, home health aides are selected on the basis of such factors as a sympathetic attitude toward the care of the sick, ability to read, write, and carry out directions, and maturity and ability to deal effectively with the demands of the job. They are closely supervised to ensure their competence in providing care. <u>418.94 Probes:</u> How does the hospice ensure that home health aides and homemakers are proficient to carry out their assignments in a safe, efficient and effective manner? How does the hospice monitor the assignments of aides to match the skills needed for individual patients?

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L210	418.94(a) Standard: Supervision. A registered nurse must visit the home site at least every two weeks when aide services are being provided, and the visit must include an assessment of the aide services.	If aides are providing services under arrangement or contract, how does the hospice ensure that the aides providing patient care have the appropriate competency skills? 418.94(a) Guidelines: The supervisory visit to the patient's residence at least every 2 weeks to assess relationships and determine whether goals are being met may occur either when the aide is present so that the RN can observe and assist the aide, or when the aide is absent. Supervisory visits may be made in conjunction with a professional visit to provide services. These visits must be documented and recorded in the patient's clinical record. 418.94(a) Probe: How does the hospice schedule supervisory visits so that aide services can be evaluated? 418.94(b) Guidelines: Aide assignments must consider the skills of the aide, the amount and kind of supervision needed, specific nursing or therapy needs of the patient, and the capability of the patient's caregiver/family. Notes by the aide should be dated and signed. 418.94(b) Probe: What evidence is there in the clinical record that the aide reports significant patient information to the appropriate person designed to receive this information? How does the hospice communicate with the aides and make them aware of the specific duties that they are expected to perform? How does the hospice ensure that the aide adheres to the plan of care? 418.96 Probe: How does the hospice ensure that medical supplies are available on a 24 hour basis when needed? Is there any indication in the records that a patient has been unable to obtain relief from uncomfortable symptoms due to non-compliance with this regulation?
L211	418.94(b) Standard: Duties. Written instructions for patient care are prepared by a registered nurse. Duties include, but may not be limited to, the duties specified in §484.36(c) of this chapter.	
L212	418.96 Condition of participation-Medical Supplies.	

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L213	Medical supplies and appliances including drugs and biologicals, must be provided as needed for the palliation and management of the terminal illness and related conditions.	
L214	418.96(a) Standard: Administration. All drugs and biologicals must be administered in accordance with accepted standards of practice.	
L215	418.96(b) Standard: Controlled drugs in the patient's home. The hospice must have a policy for the disposal of controlled drugs maintained in the patient's home when those drugs are no longer needed by the patient.	418.96(b) Guidelines: Controlled drugs are those subject to the Controlled Substance Act of 1970. The hospice need only have a written policy for disposal of controlled drugs maintained in the patient's home when they are no longer needed. The term "drugs that are no longer needed" means those drugs that have been discontinued by the physician or are remaining at the time of death. 418.96(b) Probes: What evidence is there to indicate that the staff follows the policy of the hospice in this matter?
	418.96(c) Standard: Administration of drugs and biologicals.	
L216	Drugs and biologicals are administered only by the following individuals: (1) A licensed nurse or physician.	
L217	(2) An employee who has completed a State-approved training program in medication administration.	

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L218	(3) The patient if his or her attending physician has approved.	
L219	(4) Any other individual in accordance with applicable State and local laws. The persons, and each drug and biological they are authorized to administer, must be specified in the patient's plan of care.	
L220	418.98 Conditions of participation-Short term inpatient care.	418.98 Guidelines: The key to surveying the adequacy of inpatient care services for hospice patients is to examine the actual care provided to the hospice patient in the inpatient facility and see how it relates to the assessment and plan of care developed by the hospice in conjunction with the facility's documented agreement with the hospice with respect to its patients.
L221	Inpatient care must be available for pain control, symptom management and respite purposes, and must be provided in a participating Medicare or Medicaid facility.	
	418.98(a) Standard: Inpatient care for symptom control.	
L222	Inpatient care for pain control and symptom management must be provided in one of the following: (1) A hospice that meets the condition of participation for providing inpatient care directly as specified in §418.100.	

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L223	(2) A hospital or a SNF that also meets the standards specified in §418.100(a) and (e) regarding 24-hour nursing service and patient areas.	
	418.98(b) Standard: Inpatient care for respite purposes.	
L224	Inpatient care for respite purposes must be provided by one of the following: (1) A provider specified in paragraph (a) of this section.	
L225	(2) An ICF that also meets the standards specified in §418.100(a) and (e) regarding 24-hour nursing service and patient areas.	
L226	418.98(c) Standard: Inpatient care limitation. The total number of inpatient days used by Medicare beneficiaries who elected hospice coverage in any 12-month period preceding a certification survey in a particular hospice may not exceed 20 percent of the total number of hospice days for this group of beneficiaries.	418.98 (b)(2) Guidelines: The Omnibus Budget Reconciliation Act of 1987 eliminated the SNF/ICF distinction, based on levels of care, and included a SNF/NF distinction, based on source of certification (i.e., Medicare/Medicaid). 418.98(c) Guidelines: This standard applies to Medicare beneficiaries only. Compliance with this regulation is based on the total number of Medicare beneficiaries enrolled in the hospice program, and not on a case-by-case determination.

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L227	418.98(d) Standard: Exemption from limitation. Until October 1, 1986, any hospice that began operation before January 1, 1975 is not subject to the limitation specified in paragraph (c).	
L301	418.100 Condition of Participation: Hospices that provide inpatient care directly. A hospice that provides inpatient care directly must comply with all of the following standards.	
	(a) Standard: Twenty-four hour nursing services.	418.100(a) Guidelines: Twenty-four hour nursing care requires that the hospice have the number and type of personnel sufficient to meet the total needs of the patient. A registered nurse must be on duty in the facility during each shift. 418.100(a) Probes: How does the hospice determine that there are enough personnel present to assure that adequate safety measures are in place for the patients and that the routine, special and emergency needs of all patients are met at all times? How does the hospice ensure that its personnel respond promptly to patient calls?
L302	(1) The facility provides 24-hour nursing services which are sufficient to meet total nursing needs and which are in accordance with the patient plan of care. Each patient receives treatments, medication, and diet as prescribed, and is kept comfortable, clean, well-groomed, and protected from accident, injury, and infection.	
L303	(2) Each shift must include a registered nurse who provides direct patient care.	

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L304	(b) Standard: Disaster preparedness. The hospice has an acceptable written plan, periodically rehearsed with staff, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from such disasters.	418.100(b) Guidelines: The hospice should tailor its disaster plan to its geographic location and facility residents. The purpose of the periodic rehearsal is to test the efficiency, knowledge, and response of staff personnel in the event of an emergency. Changes in physical plan or changes external to the facility can also cause a review of the disaster plan. The disaster plan should include, but not be limited to the following: o Assignment of personnel for specific responsibilities; o Procedures for prompt identification and transfer of patients and records to an appropriate facility; o Fire and/or other emergency drills, in accordance with the Life Safety Code; o Procedures covering persons in the facility and in the community in case of external disasters, i.e., hurricanes, tornadoes, earthquakes; and o Arrangements with community resources in the event of a disaster. 418.100(b) Probes: Where does the hospice keep its dated, written report and evaluation of each drill? Are staff able to answer questions about what to do in an emergency i.e., fire in a patient's room? Is there evidence that drills were held on all shifts as required by the Life Safety Code? How does the hospice ensure that each staff member is aware of what to do in an emergency? What does the written emergency procedure plan contain? What procedure does the hospice follow for notifying people in an emergency, including the physician, if the attending physician is unavailable?
	(c) Standard: Health and safety laws.	418.100(c) Guidelines: Compliance with State law does not include a requirement that the freestanding inpatient unit of the hospice be licensed by the State. However, the unit must meet other applicable State laws relevant to health and safety.

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L305	The hospice must meet all Federal, State, and local laws, regulations, and codes pertaining to health and safety, such as provisions regulating-	
L306	(1) Construction, maintenance, and equipment for the hospice;	
L307	Sanitation;	
L308	(3) Communicable and reportable diseases; and	
L309	(4) Post mortem procedures.	
	(d) Standard: Fire protection. (1) Except as provided in paragraphs (d)(2) and (3) of this section, the hospice must meet the provisions of the 1985 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference) that are applicable to hospices.	418.100(d) Guidelines: This aspect of the survey should be conducted by a qualified Life Safety Code surveyor using the appropriate fire safety survey report form. Since an inpatient hospice unit must meet the Health Care Occupancy Chapter of the Life Safety Code, it is surveyed the same as hospitals and SNFs. See §§2470 - 2480. Also, see Appendix I. If you observe fire hazards or possible deficiencies in life safety from fire, notify the designated State fire authority or the RO
	(2) In consideration of a recommendation by the State survey agency, HCFA may waive, for periods deemed appropriate, specific provisions of the Life	

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	Safety Code which, if rigidly applied would result in unreasonable hardship for the hospice, but only if the waiver would not adversely affect the health and safety of the patients.	
	(3) Any hospice that, on May 9, 1988, complies with the requirements of the 1981 edition of the Life Safety Code, with or without waivers, will be considered to be in compliance with this standard, as long as the hospice continues to remain in compliance with that edition of the Life Safety Code.	
	(4) Any facility of two or more stores that is not of fire resistive construction and is participating on the basis of a waiver of construction type or height, may not house blind, nonambulatory, or physically handicapped patients above the street-level floor unless the facility- (i) Is one of the following construction types (as defined in the Life Safety Code): (A) Type II (1, 1, 1)-protected non-combustible. (B) Fully sprinklered Type II (0, 0, 0)-non-combustible. (C) Fully Sprinklered Type III (2, 1, 1)-protected ordinary. (D) Fully sprinklered Type V (1, 1, 1)-protected wood frame; or	

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	(ii) Achieves a passing score on the Fire Safety Evaluation System (FSES).	
	(e) Standard: Patient areas.	
L310	(1) The hospice must design and equip areas for the comfort and privacy of each patient and family members.	
L311	(2) The hospice must have- (i) Physical space for private patient/family visiting;	
L312	(ii) Accommodations for family members to remain with the patient throughout the night;	
L313	(iii) Accommodations for family privacy after a patient's death; and	
L314	(iv) Decor which is homelike in design and function	
L315	(3) Patients must be permitted to receive visitors at any hour, including small children.	410.100(e)(iv) Guidelines: A homelike decor is one that deemphasizes the institutional character of the setting to the extent possible, and allows the patient to use those personal belongings that support a homelike environment.

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	(f) Standard: Patient rooms and toilet facilities.	418.100(f) Guidelines: In addition to a clean, comfortable bed, each patient should have at least a place to put personal effects, such as pictures and a clock, furniture suitable for the comfort of the patient and visitors (e.g., a chair), and adequate lighting suitable to the tasks the patient chooses to perform, or the hospice staff must perform. To ensure privacy in multi-patient rooms, each bed should have flame retardant cubicle curtains, moveable screens, or other acceptable means of providing full privacy.
L316	Patient rooms are designed and equipped for adequate nursing care and the comfort and privacy of patients.	
L317	(1) Each patient's room must- (i) Be equipped with or conveniently located near toilet and bathing facilities;	418.100(f)(1)(i): "Toilet facility" means a space that contains a lavatory and a toilet. Each floor has at least one toilet facility and shower stall large enough to accommodate a wheelchair and patient transfer.
L318	(ii) Be at or above grade level;	418.100(f)(ii): "At or above grade level" means a room in which the floor is at or above ground level.
L319	(iii) Contain a suitable bed for each patient and other appropriate furniture;	
L320	(iv) Have closet space that provides security and privacy for clothing and personal belongings;	418.100(f)(iv): Storage space for personal belongings should be accessible to the patient and protected from casual access by others.
L321	(v) Contain no more than four beds;	
L322	(vi) Measure at least 100 square feet for a single patient room or 80 square feet for each patient for a multipatient room; and	

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L323	(vii) Be equipped with a device for calling the staff member on duty.	418.100(f)(1)(vii): Call bells or other communication mechanisms must be placed within easy reach of the patient and must be functioning properly.
	(2) For an existing building, HCFA may waive the space and occupancy requirements of paragraphs (f)(1)(v) and (vi) of this section for as long as it is considered appropriate if it finds that- (i) The requirements would result in unreasonable hardship on the hospice if strictly enforced; and (ii) The waiver serves the particular needs of the patients and does not adversely affect their health and safety.	
L324	The hospice must-(1) Provide an adequate supply of hot water at all times for patient use; and	
L325	(2) Have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by patients.	
L326	(h) Standard: Linen. The hospice has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.	418.100(h) Guidelines: The linen supply must be adequate to accommodate the number of beds and the number of incontinent patients on a daily basis, including week-ends and holidays. Soiled linen and clothing should be collected and enclosed in suitable bags or containers in well ventilated areas, separate from clean linen and not permitted to accumulate in the facility.

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L327	(I) Standard: Isolation areas. The hospice must make provision for isolating patients with infectious diseases.	418.100(h) Probes: What is the hospice's policy on the frequency of linen change? How does the hospice store the clean linen to keep it clean, dry, and dust-free? How does the hospice keep soiled linen separate from the ironing, folding, and storage of clean linen? 418.100(I) Guidelines: The purpose of the isolation areas is to prevent the spread of infection and protect the patients, staff and visitors from infection. Infection control is a mechanism by which the adherence, colonization, or invasion of an infectious organism is prevented. The hospice should institute the most current recommendations of The Centers for Disease Control and Prevention (CDC) relative to the specific infection(s) and communicable disease(s). The current references on infection control published by the CDC are Guidelines for Prevention and Control of Nosocomial Infections; and Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities. The hospice provisions for isolating patients with infectious diseases should include: o Definition of nosocomial infections and communicable diseases; o Measures for assessing and identifying patients and health care workers (HCWs) at risk for infections and communicable diseases; o Measures for prevention of infections, especially those associated with immunosupressed patients and other factors which compromise a patient's resistance to infection; o Measures for prevention of communicable disease outbreaks, especially tuberculosis; o Provision of a safe environment consistent with the current CDC recommendations for the identified infection and/or communicable disease; o Isolation procedures and requirements for infected or immunosupressed patients; o Use and techniques for universal precautions; o Methods for monitoring and evaluating practices of asepsis; o Care of contaminated laundry, i.e., clearly marked bags and separate handling procedures;

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		o Care of dishes and utensils, i.e., clearly marked and handled separately; o Use of any necessary gowns, gloves or masks posted and observed by staff, visitors, and anyone else in contact with the patient; and o Techniques for handwashing, respiratory protection, asepsis sterilization, disinfection, needle disposal, solid waste disposal, as well as any other means for limiting the spread of contagion; o Orientation of all new hospice personnel to infections, to communicable diseases and to the infection control program; and o Employee health policies regarding infectious diseases, and when infected or ill employees must not render direct patient care. The facility should isolate infected patients only to the degree needed to isolate the infecting organism. The method should be the least restrictive possible while maintaining the integrity of the process and the dignity of the patient. 418.100(i) Probes: What evidence is there that staff members are aware of infection control and measures to prevent cross-contamination, as evidenced by washing their hands and/or changing gloves after performing personal care, when they leave an isolation area, when performing tasks among individuals, and any other time that would provide the opportunity for cross-contamination to occur? What infection control policies does the hospice use for persons with AIDS or hepatitis B? How does the hospice define and dispose of infected waste? How does the hospice control the spread of infection by persons who visit an infected patient? What system is in place to prevent staff personnel who have been diagnosed with a communicable disease from transmitting this disease to patients/caregivers or other staff? Is there evidence that universal precautions are being followed?
	(j) Standard: Meal service, menu planning, and supervision.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
L328	The hospice must- (1) Serve at least three meals or their equivalent each day at regular times, with not more than 14 hours between a substantial evening meal and breakfast	418.100(j)(1) Guidelines: Professional judgement may dictate that meal service is adjusted to meet variations in individual patients' conditions. This may include offering smaller, more frequent meals, or postponing breakfast or other meals to honor a patient's request (i.e., to sleep).
L329	(2) Procure, store, prepare, distribute, and serve all food under sanitary conditions;	418.100(j)(2) Guidelines: "Sanitary conditions" means storing, preparing, distributing, and serving food to properly prevent food-borne illness. Food should be stored at appropriate temperatures. Prevention of food-borne illness focuses on potentially hazardous foods; those subject to continuous time/temperature controls in order to prevent either the rapid and progressive growth of infections or toxigenic microorganisms. Perishable foods which consist of milk or milk products, meat, poultry, fish, or shellfish are maintained at safe temperatures: 45 degrees fahrenheit or below, or 140 degrees fahrenheit or above from time of preparation until served to the patient. Food is covered to prevent contamination during transportation. Handwashing facilities, including hot and cold water, soap, individual towels (preferably disposable) are provided in the food preparation areas. Waste, which is not disposed of by mechanical means, is kept in leak-proof, non-absorbent containers with close fitting lids, and is disposed of daily. Non-disposable containers are maintained in sanitary condition. Outside storage of filled disposable bags is not acceptable. Liquid wastes resulting from compacting must be disposed of as sewage. All sewage, including liquid waste, is properly disposed of by a public sewerage system or by a sewerage disposal system constructed and operated in accordance with State or local law.
L330	(3) Have a staff member trained or experienced in food management or nutrition who is responsible for- (i) Planning menus that meet the nutritional needs of each patient, following the orders of the patient's physician and, to the extent medically possible, the	418.100(j)(3) Guidelines: If the staff member responsible for dietary services is not a dietitian, it is recommended, but not required, that this person:

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	recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences (Recommended Dietary Allowances (9th ed., 1981) is available from the Printing and Publications Office, National Academy of Sciences, Washington, D.C. 20418); and	o Be a graduate of a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association; o Be a graduate of a State approved course that provides 90 or more hours of classroom instruction in food service supervision and has experience as a supervisor in a health care institution with consultation from a dietitian; or o Have training and experience in food service supervision and management in the military service equivalent in content to a dietetic technician or dietetic assistant training program, correspondence or classroom, approved by the American Dietetic Association.
L331	(ii) Supervising the meal preparation and service to ensure that the menu plan is followed; and	The hospice concept demands more leniency than a 3-meal-a-day schedule. Patients who could benefit from frequent, small, or mechanically-altered meals should be offered them. Meals are palatable and attractively served at the appropriate temperature.
L332	(4) If the hospice has patients who require medically prescribed special diets, have the menus for those patients planned by a professionally qualified dietitian and supervise the preparation and serving of meals to ensure that the patient accepts the special diet.	<u>418.100(j)(3) Probes:</u> How does the hospice plan menus to meet the patients' symptomatic and nutritional needs, or to support the palliative treatment for which patients are there? What arrangements does the hospice make to serve meals at the proper temperature and in a form to meet the patients' needs? Who is responsible for recording the patient's response to the diet in the clinical record? What evidence exists that the dietitian reviews the patient's response to the diet and advises modification if necessary? <u>418.100(j)(4) Guidelines:</u> It is recommended that a professionally qualified dietitian be a person who: (i) Is registered or eligible for registration by the American Dietetic Association; or (ii) Has a baccalaureate degree with major studies in food and nutrition, dietetics or food service management.
	<u>(k) Standard: Pharmaceutical services.</u>	
L333	The hospice provides appropriate methods and procedures for the	<u>418.100(k) Guideline:</u> Drugs and biological ordered by a physician must be made available to the patient insofar as they are covered by the Medicare or Medicaid programs. All drugs and biologicals must be available to meet patients' needs on a 24-hour basis.

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	dispensing and administering of drugs and biologicals. Whether drugs and biologicals are obtained from community or institutional pharmacists or stocked by the facility, the facility is responsible for drugs and biologicals for its patients, insofar as they are covered under the program and for ensuring that pharmaceutical services are provided in accordance with accepted professional principles and appropriate Federal, State, and local laws.	
L334	(1) Licensed pharmacist. The hospice must- (i) Employ a licensed pharmacist; or	
L335	(ii) Have a formal agreement with a licensed pharmacist to advise the hospice on ordering, storage, administration, disposal, and recordkeeping of drugs and biologicals.	
L336	(2) Orders for medications. (i) A physician must order all medication for the patient.	418.100(k)(2) Probe: How does the hospice ensure that there is a valid order for all medications given to the patient?

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L337	(ii) If the medication order is verbal- (A) The physician must give it only to a licensed nurse, pharmacist, or another physician; and	
L338	(B) The individual receiving the order must record and sign it immediately and have the prescribing physician sign it in a manner consistent with good medical practice.	
L339	(3) Administering medications. Medications are administered only by one of the following individuals: (1) A licensed nurse or physician.	418.100(k)(3) Guideline: To evaluate the accuracy of the drug distribution system, refer to Appendix P. See the Interpretive Guideline for medication error at §483.25(m). If you observe errors, note their frequency and nature, any corrective action taken, and the people notified. 418.100(k)(3) Probe: What monitoring systems does the hospice use to assure that each patient receives drugs, without medication errors, in a timely manner?
L340	(ii) An employee who has completed a State-approved training program in medication administration.	
L341	(iii) The patient if his or her attending physician has approved.	
L342	(4) Control and accountability. The pharmaceutical services has procedures for control and	418.100(k)(4) Guideline: The individual medication record may serve as the record of receipt and disposition of all controlled drugs when the unit dose and individual prescription drug disposition systems are used. However, if a floor stock system is used, a separate record system will have to be maintained for receipt and disposition of these drugs.

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	accountability of all drugs and biologicals throughout the facility. Drugs are dispensed in compliance with Federal and State laws. Records of receipt and disposition of all controlled drugs are maintained in sufficient detail to enable an accurate reconciliation. The pharmacist determines that drug records are in order and that an account of all controlled drugs is maintained and reconciled.	
L343	(5) Labeling of drugs and biologicals. The labeling of drugs and biologicals is based on currently accepted professional principles, and includes the appropriate accessory and cautionary instructions, as well as the expiration date when applicable.	418.100(k)(5) Guideline: Each patient's individual drug container also contains his/her full name, the prescribing physician's name, and the name, strength and quantity of the drug dispensed. Each floor stock drug container should also bear the name and strength of the drug and the lot and control number. Each single unit package should bear the name and strength of the drug and the lot and control number, and be clearly identified with the patient's full name and the prescribing physician's name. Drug containers with illegible, damaged, incomplete or missing labels should be returned to the pharmacist for proper labeling.
L344	(6) Storage. In accordance with State and Federal laws, all drugs and biologicals are stored in locked compartments under proper temperature controls and only authorized personnel have access to the keys. Separately locked compartments are provided for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention & Control Act of 1970 and other drugs subject to abuse,	418.100(k)(6) Guidelines: Compartments in the context of these regulations include, but are not limited to, drawers, cabinets, rooms, refrigerators, and carts. The provisions for "authorized personnel" to have access to keys must be determined by the hospice management in accordance with Federal, State, and local laws and facility practice. No discontinued or outdated or deteriorated drugs and/or biologicals are available for use in the hospice. "Separately locked" means that the key to the separately locked Schedule II drugs is not the same key that is used to gain access to the non-Schedule II drugs. Drugs brought to the facility by the patient are used only if they have been positively identified with the correct name and strength. They are used only with written orders from the physician.

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	except under single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected. An emergency medication kit is kept readily available.	418.100(k)(6) Probe: How are all drugs and biologicals stored?
L345	(7) Drug disposal. Controlled drugs no longer needed by the patient are disposed of in compliance with State requirements. In the absence of State requirements, the pharmacist and a registered nurse dispose of the drugs and prepare a record of the disposal.	

A P P E N D I X N

Surveyor Procedures for Pharmaceutical Service Requirements in Long-Term Care Facilities

APPENDIX N

Surveyor Procedures for Pharmaceutical Service Requirements in Long-Term Care Facilities

Part One: Indicators for Surveyor Assessment of the Performance of Drug Regimen Reviews

I. Proper Use of Indicators
II. Indicators for Assessing Drug Reviews

Part Two: Surveyor Methodology for Detecting Medication Errors

I. Medication Error Detection Methodology
II. Reducing Time Required for Surveying Other Drug Standards
III. Rules for Determining Medication Errors
IV. When to Write a Deficiency for Medication Errors
V. How to Calculate a Medication Error Rate
VI. Significant and Non Significant Medication Errors

APPENDIX N

SURVEYOR PROCEDURES FOR PHARMACEUTICAL SERVICE REQUIREMENTS IN LONG-TERM CARE FACILITIES

PART ONE

INDICATORS FOR SURVEYOR ASSESSMENT OF THE PERFORMANCE OF DRUG REGIMEN REVIEWS

Skilled Nursing Facilities (SNFs) and Intermediate Care Facilities (ICFs) must review the patient's drug regimen at least monthly (42 CFR 405.1127(a) and 42 CFR 442.336(a)). In intermediate care facilities for the mentally retarded (ICFs/MR) such reviews must be performed on a regular basis, at least quarterly (42 CFR 483.460(j)(1)). The reviews must be performed by a pharmacist. Information collected (e.g., drug administration records, physician orders, laboratory reports) is analyzed to determine whether there are any potential problems with the patient's drug therapy, and whether such drug therapy is achieving the stated objectives established by the physician for that patient. If there are potential problems, or if stated objectives are apparently not being achieved, the pharmacist must notify the attending physician.

I. PROPER USE OF INDICATORS

The word indicator describes what you discern as patterns of performance by the pharmacist in the conduct of the required drug regimen reviews. Most of these indicators, taken individually, could not lead to a conclusive finding of compliance or noncompliance with the drug regimen review requirements. However, together with the compliance history of the facility, they could represent reasonable evidence whether the pharmacist is adequately performing drug regimen reviews. If there is a high degree of deviation from these indicators, good reasons for the deviation must be evident from the patient's record. They may often be learned from the pharmacist and, for this reason, it is recommended that the pharmacist be present during the survey of the drug regimen review requirement.

When conducting surveys of SNFs participating in the Medicare program, for the survey to be considered valid, evaluate the pharmacy condition of participation by referring to these indicators. Under the Medicaid program, States have the choices of using these indicators or, alternatively, HCFA accepts other survey criteria developed by the State if it establishes that its criteria are, at a minimum, equal to these indicators in terms of their reliability and objectivity.

II. INDICATORS FOR ASSESSING DRUG REGIMEN REVIEWS

A. Reviews Performed Versus Average Census.--Compare the number of drug regimen reviews performed to the average census of the facility. If the average census is 100, the number of reviews that would have been performed per month would be about 100. However, this simple indicator is not absolute. Allow tolerances. For example, the pharmacist may have reviewed only 50 percent of the patients in a particular month, but the other 50 percent are scheduled for review the day after the survey. If the number of reviews falls significantly short of the patient census over a number of months, a noncompliance finding is in order.

In ICFs/MR, reviews need be performed only on a quarterly basis. Thus, modify this indicator in the ICF/MR to state that all patients are reviewed quarterly rather than monthly.

B. Reviews Should Be Performed In The Facility.--A pharmacist reviewer cannot be required to perform reviews in the facility. The regulations do not state where the reviews must be performed. However, in order to perform acceptable reviews, the facility's reviewer must be examining data sources such as the patient's drug administration record, physician orders, nursing notes, and laboratory reports. For all practical purposes these data sources are only located in the facility. Thus, to adequately perform reviews, the pharmacist should conduct them in the facility.

C. Average Prescription Utilization.--In 1974, the average prescription utilization per SNF patient was approximately 6.1. The current average is probably unchanged. As a general rule, one could question the adequacy of drug reviews if the facility's average prescription utilization were about 6 per patient. There are qualifications to this indicator:

- o The 6.1 average is a national average. Regional and State verifications can be significantly different. The average in the State may be more meaningful. The Medicaid Management Information System, if one is available, can assist in supplying this information.

- o The nature of the patient population (e.g., a high number of patients with multiple chronic diseases) may indicate a higher utilization.

- o The assumption that drug regimen reviews reduce utilization may not be true. A drug regimen review may result in additional drug utilization.

- o The pharmacist may be performing good reviews and recommending that drugs be discontinued, but the physician may not agree.

o Your analysis of the trend in prescription utilization is critical. The pharmacist may be changing attitudes about drug therapy, and a slow improvement may be evolving. Thus, if the average is higher than 6, but the trend is toward reduction, the pharmacist may be adequately performing drug reviews.

o In an ICF/MR, drug utilization is usually significantly lower (approximately 3 per patient per month.) ICFs' drug utilization is usually comparable to SNFs.

In order to estimate the average prescription utilization, examine a sufficient number of charts to establish a pattern. It is not necessary to calculate an exact average. In determining the average, include all legend and over-the-counter (OTC) drugs.

Count as one prescription any drug order, including as needed (PRN) orders, if one dose has been administered in the last 30 days. If a drug has been ordered but not administered in the last 30 days, do not count it in the average. Count combination drugs (e.g., aspirin and codeine) as one prescription.

D. Excessive Reviews on The Same Date.--The ability of a pharmacist to review patient records is finite. Question the adequacy of review if more than 100 patients have been reviewed on the same day by the same reviewer.

E. Apparent Irregularities (Potential Drug Therapy Problems).--
Subsection E.2. lists drug therapy circumstances which may constitute drug irregularities (potential drug therapy problems). The pharmacist should address them every time they are encountered. Initially learn five to ten of them and use them in your surveys. Learn an additional five to ten more, and so forth until all are learned.

1. Rules for Applying Apparent Irregularities

o The pharmacist conducting reviews is responsible for identifying apparent irregularities and notifying an individual in authority of the need to correct the potential problem.

o You are responsible for determining whether such identification and notification has taken place. Do not go beyond determining if identification and notification has occurred. It is not necessary to ascertain the disposition of the recommendation made. Inquiry into the specific treatment or outcome could be construed as Federal interference with the practice of medicine, which is prohibited by §1801 of the Act.

o A record of drug regimen reviews must be maintained in the facility to demonstrate that such reviews have been performed. This record may or may not be a part of the patient's medical record depending upon the facility's policy. Each patient must be identified, and documentation of one of the following circumstances must exist:

- If no potential problems were found, the pharmacist reviewer must have included a signed and dated statement to this effect in the drug regimen review record.

- If a potential problem was found and the pharmacist reviewer deemed it not significant, he or she must have included a signed and dated statement in the record which describes the situation.

- If a potential significant problem was found, the pharmacist reviewer must have included a signed and dated statement in the record describing the situation and indicating that this information was communicated to an individual with authority to correct it, usually the attending physician.

- The pharmacist reviewer need not have documented the identification and notification every month (or quarter in ICFs/MR) even if the apparent irregularity continues, if it has been deemed insignificant by the pharmacist reviewer, or it has been deemed significant, but the recommendation has been rejected by the individual having authority to correct it.

Under these circumstances, the facility's reviewer may document that he or she has identified an apparent irregularity and notified a person having authority to correct the potential problem on an annual basis. This documentation should appear in whatever record the facility uses for documenting drug regimen reviews.

2. List of Apparent Irregularities.--These drug therapy circumstances may constitute drug irregularities (potential drug therapy problems).

NOTE: Generic names are noted only when they are in common usage and are designated by lower case type.

o Multiple orders of the same drug for the same patient by the same route of administration (e.g., the same chemical entity by different brand names);

o Drugs administered in disregard of established stop order policies;

o As needed (PRN) drug orders administered as directed every day for more than 30 days;

o Patients receiving three or more laxatives concurrently. Sequential use need not be questioned. Examples of commonly used laxatives are:

Agoral	Dulcolax	mineral oil
Cascara Sagrada	Effersyllium	Modane Bulk
Chronulac	Fleet's Enema	Modane Soft
Colace	glycerin suppositories	Neoloid
Dialose	Haley's M.O.	Peri-Colace
docusate sodium	Konsyl	Senokot
Dorbantyl	Metamucil	Surfak
Doxinate	milk of magnesia (MOM)	

o Use of antipsychotics or antidepressants for fewer than three days. (Exception: Compazine used as an antinausant.)

o Continuous use of the following hypnotic (sleep induction) drugs for more than 30 days.

	Usual Maximum Single Dosage For Age 65 & Over	Usual Maximum Single Dosage
Amytal	150 mg.	300 mg.
Butisol	100 mg.	200 mg.
chloral hydrate	750 mg.	1500 mg.
Dalmane	15 mg.	30 mg.
Doriden	500 mg.	1000 mg.
Halcion	0.25 mg.	0.5 mg.
Nembutal	100 mg.	200 mg.
Noctec	750 mg.	1500 mg.
Noludar	200 mg.	400 mg.
Placidyl	500 mg.	1000 mg.
Restoril	15 mg.	30 mg.
Seconal	100 mg.	200 mg.

o Use of two or more hypnotic drugs listed above at the same time, or administered in excess of the listed maximum doses;

o Use of two or more of the following antipsychotic drugs at the same time.

	Usual Maximum Daily Antipsychotic Dosage for Ages 65 and Over	Usual Maximum Daily Antipsychotic Dosage
chlorpromazine	800 mg.	1600 mg.
Haldol	50 mg.	100 mg.
Loxitane,	125 mg.	250 mg.
Mellaril	400 mg.	800 mg.
Moban, Lidone	112 mg.	225 mg.
Navane	30 mg.	60 mg.
Proketazine	200 mg.	400 mg.
Prolixin,	20 mg.	40 mg.
Quide	80 mg.	160 mg.
Repoise	80 mg.	160 mg.
Serentil	250 mg.	500 mg.
Stelazine	40 mg.	80 mg.
Taractan	800 mg.	1600 mg.
thioridazine	400 mg.	800 mg.
Thorazine,	800 mg.	1600 mg.
Tindal	150 mg.	300 mg.
Trilafon	32 mg.	64 mg.
Vesprin	100 mg.	200 mg.

o Use of the antipsychotic drugs listed in excess of their listed daily dosage maximums;

o Use of a listed antipsychotic drug unless the clinical record documents that one of the following specific conditions exists:

(1) Schizophrenia
(2) Schizo-affective disorder
(3) Delusional disorder
(4) Psychotic mood disorders (including mania and depression with psychotic features)
(5) Acute psychotic episodes
(6) Brief reactive psychosis
(7) Schizophreniform disorder
(8) Atpical psychosis
(9) Tourette's disorder
(10) Huntington's disease
(11) Organic mental syndromes (including dementia) with associated psychotic and/or agitated features as defined by:

(a) Specific behaviors (e.g. biting, kicking, scratching) which are quantitatively (e.g. number of episodes) documented by the facility and which cause the resident to:

- Present a danger to themselves
- Present a danger to others
- (including staff) or
- Actually interfere with staff's ability to provide care,

or

(b) Continuous crying out, screaming, yelling or pacing if these specific behaviors cause an impairment in functional capacity and if they are quantitatively (e.g. periods of time) documented by the facility, or

(c) Psychotic symptoms (hallucinations, paranoia, delusions) not exhibited as specific behaviors listed in "a" and "b" above if these behaviors cause an impairment in functional capacity.

(12) Short term (7 days) symptomatic treatment of hiccups, nausea, vomiting or pruritus.

o Use of the antipsychotic drugs in the absence of gradual dose reduction attempted every six months after therapy began. Gradual dose reductions are not necessary if within the last six months the resident has had a gradual dose reduction and the dose has been reduced to the lowest possible dose to control symptoms.

o Use of a listed antipsychotic drug when one or more of the following behaviors is the only indication for use:

(1) Wandering
(2) Poor self care
(3) Restlessness
(4) Impaired memory
(5) Anxiety
(6) Depression
(7) Insomnia
(8) Unsociability
(9) Indifference to surroundings
(10) Fidgeting
(11) Nervousness
(12) Uncooperativeness
(13) Unspecified Agitation

o The use of a p.r.n. antipsychotic drug more than five times in any seven day period without a review of the resident's condition by a physician.

o Use of the following anxiolytic drugs when their dosages exceed the following maximums:

	Usual Daily Dosage For Age 65 And Over & Age 12 And Under	Usual Daily Dosage Age Under 65 And Over 12
Ativan	3 mg./day	6 mg./day
Azene	30 mg./day	60 mg./day
Centrax	30 mg./day	60 mg./day
chlordiazepoxide	40 mg./day	100 mg./day
diazepam	20 mg./day	60 mg./day
Equanil,	600 mg./day	1600 mg./day
Librium	40 mg./day	100 mg./day
meprobamate	600 mg./day	1600 mg./day
Miltown	600 mg./day	1600 mg./day
Paxipam	80 mg./day	160 mg./day
Serax	60 mg./day	90 mg./day
Valium	20 mg./day	60 mg./day
Tranxene	30 mg./day	60 mg./day
Xanax	2 mg./day	4 mg./day

o More than two changes of an antidepressant within a 7-day period. Examples of commonly used antidepressants are:

	Usual Maximum Daily Dosage For Age 65 And Over	Usual Maximum Daily Dosage
Adapin	150 mg.	300 mg.
amitriptyline	150 mg.	300 mg.
Asendin	200 mg.	400 mg.
Aventyl	75 mg.	150 mg.
Desyrel	300 mg.	600 mg.
doxepin	150 mg.	300 mg.
Elavil	150 mg.	300 mg.
imipramine	150 mg.	300 mg.
Ludiomil	150 mg.	300 mg.
Norpramin	150 mg.	300 mg.
Pamelor	75 mg.	150 mg.
Pertofrane	150 mg.	300 mg.
Sinequan	150 mg.	300 mg.
SK pramine	150 mg.	300 mg.
Surmontil	150 mg.	300 mg.
Tofranil	150 mg.	300 mg.
Vivactil	30 mg.	60 mg.

o Use of the above antidepressants listed in excess of the listed daily maximum doses;

o Patients who repeatedly lose seizure control while taking anticonvulsants (e.g., Dilantin (phenytoin), phenobarbital, Mysoline, Depakene (valproic acid));

o Patients who are taking thyroid drugs and have not had some assessment of thyroid function (e.g., Free T4 Level, T3 Resin update, Free Thyroxin update). Examples of commonly used thyroid drugs are Synthroid, Cytomel, Thyroid Extract;

o Patients who are taking the following drugs and have not had a blood pressure recorded at least weekly.

Aldomet	furosemide	Lopressor
Apresoline	hydralazine	Minipress
Blocadren	hydrochlorothiazide	propranolol
Capoten	Hydrodiuril	resperine
Catapres	Hygroton	Serpasil
chlorothiazide	Hylorel	Tenormin
Corgard	Inderal	Visken
Diuril	Ismelin	Wytensin
Dyazide	Lasix	Zaroxolyn

o Patients who are taking anticoagulant therapy and have not had some assessment of blood clotting function at least monthly. The most common blood clotting function test is prothrombin time. Examples of commonly used anticoagulants are Coumadin (warfarin), Dicumarol;

o Patients who are taking cardioactive drugs and have not had a pulse rate recorded daily in the first month of therapy and weekly thereafter, or the chart shows a pulse consistently below 60 or above 100.

Blocadren	Procan
Calan	Procardia
Corgard	Pronestyl
digoxin	propranolol
Inderal	Quinaglute
Isoptin	Quinidine
Lonoxin	Tenormin
Lopressor	Timoptic
Norpace	Viskin

o Patients who are taking insulin or oral hypoglycemics and have not had a urine sugar test at least daily or a blood sugar test at least every 60 days. Examples of commonly used hypoglycemics are: Glucotrol, Diabeta, Micronase, Orinase, Diabinese, Dymelor, Tolinase;

o Patients who are taking iron preparations, folic acid or Vitamin B 12, and have not had a red blood cell assessment (e.g., hemoglobin, hematocrit) during the first month of therapy. Examples of commonly used iron preparations are: Feosol (ferrous sulfate), Imferon, Fergon (ferrous gluconate);

o Use of Mandelamine, Hiprex, Bactrim, Septra, Macrodantin, Furdantin, or Urex in chronic urinary tract infections if a urinalysis has not been performed at least once, 30 days after therapy was initiated;

o Patients taking Mandelamine or Hiprex who have not had a urine pH determination within 30 days after therapy was initiated, or if therapy is continued when urine pH is continually above 6;

o Use of nitrofurantoin (Furadantin, Macrodantin) for conditions other than treatment or prophlaxis of urinary tract infections, or blood urea nitrogen or serum creatinine levels are not recorded on the chart;

o Three or more orders for analgesics used at the same time. Examples of commonly used analgesics are:

acetaminophen	Empirin	Nalfon
Anaprox	Empirin with Codeine	Naprosyn
aspirin	Feldine	Percodan
Clinoril	ibruprofen	Rufen
Darvocet N	Indocin	Tolectin
Darvon Compound	Meclomen	Trilisate
Demerol	meperidine	Tylenol
Dolobid	Motrin	Tylenol with Codeine

o Patients taking diuretics who have not had a serum potassium level determination within 30 days after initiation of therapy. Examples of commonly used diuretics are:

acetazolamide	Dyazide	Hydrodiuril
Aladactone	Dyrenium	Hygroton
Aldactazide	Edecrin	Lasix
Bumex	Enduron	Midamor
chlorothiazide	Esidrix	Moduretic
Diamox	furosemide	Neptazane
Diuril	hydrochlorothiazide	Zaroxolyn

o Patients taking certain diuretics and cardiotonics, e.g., Lanoxin who have not had a serum potassium determination within 30 days after initiation of the cardiotonic therapy and every 6 months thereafter;

o Patients who are taking Butazolinin, Azolid or Tandearil continuously and have not had at least one CBC determination 30 days after initiation of therapy;

o The use of cardiotonics, e.g. Lanoxin in the absence of documentation of one of the following diagnoses:

congestive heart failure
atrial fibrillation
paroxysmal supraventricular tachycardia
atrial flutter

o The use of anticholinergic therapy, e.g., Artane, Cogentin or Kemardin with antipsychotic drugs in the absence of recorded extra- pyramidal side effects, e.g., tremor, drooling, shuffling gait;

o The continuous use of antibiotic/steroidal ophthalmic preparations, e.g., Cortisporin ophthalmic, Metimyd ophthalmic or Ophthocort, for periods exceeding 14 days;

o The use of the following aminoglycosides (Garamycin, Nebcin, Amikin, Kantrex, Netromycin) in the absence of a serum creatinine determination when therapy was initiated;

o Orders for drugs for which there is a known allergy as documented in the patient's record;

o The crushing of solid dosage forms when the likely result will cause patient discomfort (e.g., Dulcolax) or undesired blood levels (e.g., Theodur).

PART TWO

METHODOLOGY FOR DETECTING MEDICATION ERRORS

Regulations for SNFs, ICFs, and ICFs/MR endeavor to minimize medication errors. For SNFs, 42 CFR 405.1124(h) states that "Drugs are administered in accordance with written orders of the attending physician." This requirement precludes drugs from being administered in any way that deviates from physicians' written orders. For ICFs, 42 CFR 442.334(a) requires that medications administered to a resident be ordered either in writing or orally by "the resident's attending or staff physician." The interpretive guideline requires that drugs and biologicals be administered as ordered by the physician; emphasis is placed on administering drugs at the prescribed time. This requirement prohibits drugs from being administered in any way other than as ordered by the physician. For ICFs/MR, 42 CFR 483.460(k)(2) requires that the facility ensure that all drugs, including those that are self-administered, be administered without error.

I. MEDICATION ERROR DETECTION METHODOLOGY

To determine medication errors, observe the administration of drugs, (preferably on several different drug "passes") and record what you observe. Reconcile your observations with the physician's drug orders to determine whether or not medication errors have occurred.

Do not rely solely on a paper review to determine medication errors. Detection of blank spaces on a medication administration record does not constitute the detection of actual medication errors. Paper review only identifies possible errors. Experience has shown that facility staff are likely to correct the paper rather than correct the errors.

A. Observation Technique.--Know without doubt, what drugs, in what strength and dosage forms, etc. are being administered. Accomplish this prior to drug administration. It may be done in a number of ways depending upon the surveyor and the drug distribution system used (e.g., unit dose, vial system, punch card).

1. Identify the Drug Product. There are two principal ways to do this. In most cases, they are used in combination.

- Identify the product by its size, shape and color. Many drug products are identifiable by their distinctive size, shape, or color. This technique is problematic because not all drugs have distinctive sizes, shapes, or colors.

o Identify the product by observing the label. When the punch card or the unit dose system is used, you can usually observe the label and adequately identify the drug product. When the vial system is used, observing the label is sometimes more difficult.

o Another method is to attach pre-numbered stickers. This is a variation to the observation technique and is described in subsection B.

2. Observe and Record the Administration of Drugs ("pass"). Follow the person administering drugs and observe patients receiving them (e.g., actually swallowing oral dosage forms). Be neutral and as unobtrusive as possible.

Make every effort to observe 20 patients from several different drug "passes" so that you have an assessment of the entire facility, rather than of one staff member or one drug pass.

Note every detail on your record of the drug administration. For example, "eye drops administered in both eyes," "nurse took pulse," "patient swallowed nitroglycerin" or "all drugs crushed and administered in apple sauce." Identifying patients can present a problem. Some long term care facilities do not use arm identification bands, or assume correctness of the patient by relying on the actions of the nurse and the response of the patient.

3. Reconcile Your Observation with Physician's Orders. Compare your observations with the most current signed orders for drugs. This comparison involves two distinct activities:

o For each drug on your list: Was it administered according to the physician's orders? For example, in the correct strength and by the correct route? Was there a valid order for the drug? Was the drug the correct one?

o For drugs not on your list: Are there orders for drugs that should have been administered but were not? Examine the record for drug orders that were not administered but should have been. You are looking for omitted doses, one of the most frequent types of errors.

You now have a complete record of what you observed and what should have occurred according to the physicians' orders. Determine the number of errors by adding the errors on each patient. Before concluding for certain that an error has occurred, discuss the apparent error with the person who administered the drugs. There may be a logical explanation for an apparent error. For example, a surveyor once observed that a patient had received Lasix 20 mg, but the order was for 40 mg. This was an apparent error in dosage. But the nurse showed the surveyor another more recent order which discontinued the 40 mg order and replaced it with the 20 mg order.

B. Variation to the Observation Technique - Use of Numbered Stickers for Product Identification.--When the vial system of drug distribution is used, the visual identification of the drug product may not always be possible. You may need to use numbered stickers attached to the vial caps to identify the drug product.

o Label drug vials with numbered stickers. Prior to the drug "pass" choose a nursing station at random. Before the preparation for administration ("pour") begins, place numbered stickers on each medication vial.

NOTE: The stickers are 3/4 inch in diameter, and can be obtained from most office supply stores. They are manufactured by both Avery and Dennison. Number the stickers in advance with consecutive numbers from 1 to about 300. Be sure to write the numbers as large as possible.

It is not necessary to place stickers on large bottles of drugs such as Gelusil or Maalox as the labels on these containers are large enough to be seen from a distance. Make sure that the "pass" to be observed includes at least 20 patients receiving drugs. (When the numbered sticker variation is used, it is, of course, impossible to observe different staff on different drug "passes", unless you watch different passes from the same nursing station.)

o Observe the preparation for "pour" and record the numbers of the drugs "poured" on the left hand column of a plain sheet of paper. If more than one unit of a drug is placed into a patient's souffle cup, write the number of units next to the drug number. For example, if 2 units of drug "214" are "poured" write "214-2." If one unit, write "214." If 3 units, "214-3." During the "pour," make sure that each unit prepared for a particular patient goes into that patient's souffle cup. Note the patient's name and room number. At this point, your record looks like this:

John Smith	214-2
Room 137B	215
	217
	220
	216

Proceed with "Observe and Record the Administration of Drugs" as described in subsection A.2.

o Decode drug sticker numbers. After the "pass," return to the drug room and record the drug name and strength which corresponds to each sticker number. Do this only for the 20 patients you have included in your study. Write the drug name and the strength next to the patient's name and room number. At this point, your record looks like:

John Smith	214-2 - Aspirin 5 gr
Room 137B	215 - Valium 5 mg
	217 - Digoxin 0.25 mg Pulse Taken
	220 - Tetracycline 250 mg
	216 - Colace

After decoding, proceed with "Reconcile your record of observation with physician's orders" as described in subsection A.3.

C. Dose Reconciliation Technique: Supplement to the Observation Technique.--When an omission error has been detected through the observation technique, the dose reconciliation technique can sometimes enable you to learn how frequently an error has occurred. Learning the frequency of an error can assist you in judging the significance of the error. (See VI. Significant and Non-Significant Medication Errors.) The dose reconciliation technique requires a comparison of the number of doses remaining in a supply of drugs with the number of days the drug has been in use and the directions for its use. For example, if a drug was in use for 5 days with directions to administer it 4 times a day, then 20 doses should have been used. If a count of the supply shows that 18 doses were used (i.e., two extra doses exist) and no explanation for the discrepancy exists (e.g., patient refused the dose, or patient was hospitalized), two omission errors may have occurred.

Use the dose reconciliation technique only in facilities that indicate the number of drugs received, and the date and the specific "pass" when that particular supply of drugs was started. Unless this information is available, do not use this technique. If this information is not available there is no Federal authority under which you may require it, except for controlled drugs.

II. REDUCING TIME REQUIRED FOR SURVEYING OTHER DRUG STANDARDS.

A. Requirements Covered by the Medication Error Detection Methodology.--The intention of certain procedural requirements located at 42 CFR 405.1124(g) is to avoid medication errors. However, compliance with these requirements is automatically verified via the medication error detection methodology. Thus, using the observation technique replaces the expenditure of surveyor time to determine compliance with the following requirements of 405.ll24(g):

- Drugs to be administered are checked against physician orders. (SNF tag F183.)
- The patient is identified prior to the administration of a drug. (SNF tag F184.)
- Drugs and biologicals are administered as soon as possible after doses are prepared. (SNF tag F187.)
- Drugs are administered by the person who prepared the doses for administration. (SNF tag F188.)

In addition to the above, the following labeling and record requirements are covered by the medication error detection methodology.

- The standard on labeling drugs and biologicals. (42 CFR 405.1127(c); SNF tag F278.)

- Each patient has an individual medication record. (42 CFR 405.1124(g); SNF tag F185.)

B. Requirements of Less Priority.--The following requirements pursue regulatory objectives that are less important than the identification and prevention of medication errors. As such, give them relatively less attention.

o Review of records of the receipt and disposition of controlled drugs (see 42 CFR 405.1127(b) or SNF Survey Report tag F276; no similar requirement for ICFs).

o Determinations of whether all drugs are locked. (See 42 CFR 405.1124(i) or SNF Survey Report tag F204; no similar requirement for ICFs).

o Review of the pharmaceutical services committee. (See 42 CFR 405.1127(d) or SNF Survey Report tag F279, F280, F281 and F283; no similar requirement for ICFs).

III. RULES FOR DETERMINING MEDICATION ERRORS

A. Timing Errors.--Count a wrong time error if the drug is administered 60 minutes earlier or later than its scheduled time. To determine the scheduled time, examine the facility's policy relative to dosing schedules. The facility's policy should dictate when it administers a.m. doses, or when it administers the first dose in a 4 times a day dosing schedule. In deciding on wrong time errors, be sensitive to the possibility of your observations slowing the drug "pass," and adjust the number of wrong times errors accordingly. Do not count wrong-time errors for drugs administered on a once-a-day basis (e.g., digoxin). Always count wrong-time errors for drugs not correctly administered in relation to meals (after meals, before meals).

B. Physician's Orders.--The latest recapitulation of the drug orders (monthly "recap") is sufficient for determining whether a valid order exists, provided the physician has signed the "recap." The signed "recap" and subsequent orders constitute a legal authorization to administer the drug. Attempts to find original orders in the physician's handwriting are usually too time consuming.

C. Reporting Errors.--Describe to the facility each error that you detect (e.g., Mary/Jones received digoxin 0.125 instead of 0.25 mg). You are not required to analyze the errors and come to any conclusions on how the facility can correct them. If you wish to offer this consultation, you are encouraged to do so. Any advice you give must not be offered as if the facility has to follow it. Do not attempt to categorize errors into various classifications (e.g., wrong dose, wrong patient). The important thing to stress is that an error occurred and that future errors must be avoided.

D. Observe Morning "Pass".--It is preferable to watch the morning drug administration pass because that is when most doses are administered in long term care facilities and hence offers the greatest opportunity to observe errors.

E. Observe Several Individuals.--Strive to observe several individuals administering drugs so that an assessment of medication errors will be more broadly based. This requires the observation of several "passes" at the same time or different times of the day. If you use numbered stickers to identify the drugs, the "passes" observed will need to come from the same drug storage area but may be administered by different individuals. In a large ICF/MR, you may need to go to several buildings in order to observe several individuals administering drugs.

IV. WHEN TO WRITE A DEFICIENCY FOR MEDICATION ERRORS

Regulations §405.1124(h) and §442.334(a) (Long Term Care Survey Report Form, Tag F174) or regulation §483.460(k)(2) (Intermediate Care Facility for the Mentally Retarded Survey Report Form Tag W369) must be marked out of compliance if you determine that medication errors are jeopardizing the health and safety of patients. Use the following criteria in deciding when to write a deficiency for medication errors:

- o If one or more significant medication error occurs (see following discussion on significant and insignificant errors), or

- o If insignificant and significant medication errors together amount to five percent or more of the total opportunities for errors.

The basis for writing a deficiency after a particular tolerance has been exceeded relates to the probability that these errors are symptomatic of a drug distribution system that is faulty and that will eventually produce significant errors that can jeopardize the health and safety of patients. The five percent minimum tolerance level is chosen on the basis of the best available information relative to what is achievable in terms of contemporary drug distribution systems, and the level of sophistication in methodologies for detecting medication errors. Only experience with these variables will permit a determination whether the five percent is appropriate or whether it should be revised.

V. HOW TO CALCULATE A MEDICATION ERROR RATE

In calculating the percentage of errors, the numerator in the ratio is the total number of errors that you observe, both significant and insignificant.
The denominator is all the doses you observed being administered plus the doses ordered but not administered. The equation for calculating a medication error rate is:

Medication Error Rate = Number of Errors Observed divided by the Opportunities for Errors x 100.

Where: Opportunities for Errors equals the number of doses administered plus number of doses ordered but not administered.

VI. SIGNIFICANT AND NON-SIGNIFICANT MEDICATION ERRORS

A. General Rules for Determining Significance.--The relative significance of medication errors is a matter of professional judgement. Surveyors who are responsible for assessing these requirements must be qualified to exercise such judgement (e.g., pharmacists, nurses). Follow three general rules in determining whether a medication error is significant or not:

1. Patient Condition.--The patient's condition is an important factor to consider. For example, a potent diuretic erroneously administered to a dehydrated patient may have serious consequences but if administered to a patient with a normal fluid balance may not. If the patient's condition requires rigid control, a single missed or wrong dose can be highly significant.

2. Drug Category.--If the drug is from a category that usually requires the patient to be titrated to a specific blood level, a single medication error could alter that level and precipitate a re-occurrence of symptoms or toxicity. This is especially true if the half life of the drug is short. Examples of drug categories which require titration of patient blood levels include anticonvulsants, anticoagulants, and antiarrhythmic, antianginal and antiglaucoma agents.

3. Frequency of Error.--If an error is occurring with any frequency, there is more reason to classify the error as significant. For example, if a patient's drug was omitted several times, as verified by reconciling the number of tablets delivered with the number administered, classifying that error as significant would be in order. This conclusion may be especially valid when taken in concert with the patient's condition and the drug category.

B. Examples of Significant and Non-Significant Medication Errors.--Examples of medication errors that have occurred in long term care facilities are presented below. Some of these are identified as significant. This designation is based upon expert opinion without regard to the status of the patient. Most experts concluded that the significance of these errors, in and of themselves have a high potential for creating problems for the typical long term care facility patient. Errors identified as non-significant have also been designated primarily upon the basis of the nature of the drug. Patient status and frequency of error could classify these errors as significant.

1. OMISSIONS (DRUGS ORDERED BUT NOT ADMINISTERED AT LEAST ONCE)

HALDOL 1mg BID	NS
MOTRIN 400 mg TID	NS
QUINIDINE 200mg TID	S
TEARISOL Drops 2 both eyes TID	NS
INDOCIN 25mg TID pc	NS
LIORESAL 10 mg TID	NS

THORAZINE 25 mg BID	NS
AMPICILLIN 500 mg TID	NS
METAMUCIL one packet BID	NS
INDERAL 20mg one every 6 hours	S
MULTIVITAMIN one daily	NS
MYLANTA SUSP. one oz. TID AC	NS
NITROL OINT. one inch	S
LIBRIUM 10mg one TID	NS
CORTISPORIN OTIC drop 4 to 5 left ear QID	NS
ALDACTONE 25 mg QID	NS

2. UNAUTHORIZED DRUG (DRUGS ADMINISTERED WITHOUT A PHYSICIAN'S ORDER)

FEOSOL	NS
COUMADIN 4 mg	S
LASIX 40 mg	S
ZYLOPRIM 100 mg	NS
TYLENOL 5 gr	NS
TRIAVIL 4-25	NS
MULTIVITAMINS	NS
MOTRIN 400 mg	NS

3. WRONG DOSE

ORDERED	ADMINISTERED	
ISOPTOCARPINE 1% one drop in the left eye TID	Three drops in each eye	NS
EPINAL 1% one drop in eyes BID	Three drops in each eye	NS
DIGOXIN 0.125 mg everyday	0.25 mg	S
LASIX 20 mg one daily	40 mg	NS
AMPHOJEL 30 cc QID	15cc	NS
SLOW K two TID	one	NS
DILANTIN 125 SUSP 12cc	2cc	S
LASIX 40 mg daily	20 mg	NS

4. WRONG ROUTE OF ADMINISTRATION

ORDERED	ADMINISTERED	
HYDERGINE 0.5 mg S.L. BID	Patient swallowed	NS
CORTISPORIN OTIC DROPS 4 to 5 left ear QID	Left Eye	S

5. WRONG DOSAGE FORM

ORDERED	ADMINISTERED	
COLACE LIQUID 100 mg BID	capsule	NS
MELLARIL 10 mg Tab TID	concentrate (If correct dose was given)	NS
DILANTIN KAPSEALS 100 mg three Kapseals p.o. HS	Prompt Phenytoin 100 mg three capsules p.o. HS	S (Parke Davis Kapseals have an extended rate of absorption. Prompt phenytoin capsules do not.)

6. WRONG DRUG

ORDERED	ADMINISTERED	
TYLENOL 325 mg	ASCRIPTIN (Routinely)	S

7. WRONG TIME

ORDERED	ADMINISTERED	
INDOCIN 25 mg PC	AC	NS
PERIACTIN 4 mg PC	AC	NS
DIGOXIN 0.25 Daily AT 8 AM	At 9:15 am	NS
TETRACYCLINE 250 mg QID AC AND HS	PC	S

S - Significant
NS - Not Significant